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ABSTRACT

This report presents a policy- and methodology-oriented discussion of factors involved in developing and analyzing quality assurance in European health care. Data are taken from research literature and interviews with representatives of national health authorities, professional organizations, and research and educational institutions. The first chapter of this report discusses a suggested conceptual framework, for a program of health care quality assurance, derived from evaluative research and industrial quality control. The second, third, and fourth chapters deal with three major variables in the framework: environment, conceptualization, and methodology. Examples of different approaches to quality assurance are given, and sources of information and measurement instruments and criteria are examined. The fifth chapter presents conclusions concerning the trends and state of quality assurance in health care. A bibliography of 179 items is appended. (FG)

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PUBLIC HEALTH IN EUROPE 16

Quality Assurance of Health Services

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Concepts and Methodology

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Preface

In 1981, the Regional Office for Europe of the World Health Organization decided to launch a new programme under the title "model health care programmes and quality assurance". The programme addresses itself to two issues: the most appropriate combination of services in the care of a patient with a given problem and the quality of health services. The focus of this book is the second issue.

Although the World Health Assembly and the WHO Regional Committee for Europe have passed no resolutions explicitly mentioning quality assurance, it was felt that the mandate to proceed is clear; quality is implicit in the WHO Constitution, in the Sixth General Programme of Work, and in the many recommendations pertaining to the establishment of norms and standards and to health services evaluation, and there is clearly a growing interest in quality assurance in the Member States.

The new programme is a natural and logical extension of previous activities that have reflected this implicit mandate. If one looks at the reports and recommendations of the working groups convened by the Regional Office, one notices the concept of quality with an increasing frequency in discussions pertaining to the evaluation of health services and the effective use of available resources. In the beginning, the notion prevailed that everybody was entitled to the best that medicine can offer. Gradually, a more resource- and cost-orientated view has emerged; it has been admitted that quality of care is often influenced by available resources, by the volume and nature of work to be done, by the methods and techniques or processes that may be used, and by the time available. The context makes it clear that these factors were not considered constraints preventing the health professionals from working at a desired higher qualitative level of care, but legitimate determinants of the optimal qualitative level.

Whatever the definition of quality chosen, many WHO working groups have underlined the desirability of assessing the quality of health services, although they have readily admitted the methodological difficulties involved. Patients' views on care as a valid criterion of quality is a recurring theme from the outset. WHO reports often reflect things in status nascendi, *before they have been generally accepted by the health professionals. Quality assurance may well still be at an early stage in Europe, but it is difficult to agree* *with the claim that advanced nations pay little attention to quality assurance and that other countries seem content to assume that competence exists and that the principal professional and governmental task in this arena is to handle matters of incompetence. There may not be many concrete activities going on, particularly in the western European countries, but the interest is marked.*

Medical practitioners have claimed that it is unlikely that the health care system can manage without production and quality control; there have been editorials calling for quality assurance; papers dealing with quality assurance have been awarded prizes; writers of review articles have identified a great number of empirical works; national task forces have recommended quality assurance; and professional bodies have vouched for it. Several countries are developing treatment protocols that can be used as yardsticks against which the quality of services can be rendered. Some countries have even enacted legislation on quality assurance, and this has been followed by a crop of papers introducing the concept to the professional. Institutions specializing in quality assurance have also been founded, such as the National Institute for Quality Assurance in Hospitals in the Netherlands. In this context, the socialist countries deserve a special mention because quality assurance in the form of specialist supervision has a long tradition in those countries and is an essential part of the health care system.

In spite of this interest, quality assurance is still a novel and nebulous concept for the majority of European health professionals. The abundant American literature on quality assurance is not very helpful because the approaches described are usually very closely tied to a particular system, which renders the American experience irrelevant for Europe. What seems to be needed is a publication that concentrates on the conceptual and methodological issues in quality assurance. This book is intended to do this. Its purpose is to cover systematically the most important concepts and methods and to supplement this discussion with relevant European examples and experiences. The book is intended primarily for medical researchers interested in designing studies related to the quality of health services, and for researchers and administrators who want to establish routine systems for assuring the high quality of their services. Policy-makers should also find it of interest, since it addresses itself to many of the controversial issues that presume a political solution.

NOTE ON TERMINOLOGY

Activities that concern the quality of health services can be divided into research and action programmes. On the one hand, research aims to clarify the concept of quality itself, to determine factors influencing quality, and to evaluate the effectiveness of quality assurance programmes in improving the quality of services. On the other hand, action programmes operate on a routine basis and aim to assess the actual level of the quality of services rendered and to improve it when the assessment indicates deficiencies.

In both research and action programmes, certain concepts are employed. Some of these will be defined in detail later in an appropriate context. However, since they have to be used from the outset, provisional definitions are given here.

Quality of health services This key concept is usually poorly defined and loosely used. I suggest the best way to achieve clarity and avoid confusion is to divide it into the following four components.

Effectiveness The relation of the actual impact of a service or programme in an operating system to its full potential impact in an ideal situation.

Efficiency The relation of the actual impact of a service or programme to its production costs.

Adequacy The relation of available services to the needs of the population.

Scientific-technical quality The level of application to care of the currently available medical knowledge and technology. When the term *quality*, without qualification, appears in the literature or in this book, it almost invariably refers to this component of the overall quality of health services.

It should be noted that *equity* has not been included in this list. It is considered to be an attribute of the entire health care system rather than of a health service. The same argument actually partly applies to adequacy as well.

Quality assessment The measurement of the actual level of the quality of services rendered.

Quality assurance The measurement of the actual level of the quality of services rendered plus the efforts to modify when necessary the provision of these services in the light of the results of the measurement.

Quality control Quality control is synonymous with quality assurance. Because of its connotations, the term is usually replaced by the more neutral quality assurance.

Introduction

In health care, the consumers, providers and planners of health services have four basic concerns: efficacy and effectiveness, efficiency, equity, and quality. These concerns constitute a logical sequence. First and above all, the health services have to be capable of producing the desired effect. However, owing to organizational, situational and other constraining factors, a service with proven efficacy, when taken into routine use, does not always achieve its full potential. As a consequence, the effectiveness of the service – the relation of its actual impact to its potential impact in an ideal situation – has to be ascertained. Effective services can, in turn, be prohibitively costly. Hence the next step consists of determining their efficiency, i.e. the relation between their actual impact and production costs. Demonstration of efficacy, effectiveness and efficiency is the task of research. Once these have been demonstrated, a policy decision concerning the combination of health services to be produced and their distribution can be made. One commonly accepted policy goal is to distribute the services equitably, i.e. in accordance with the objective and perceived health needs of the population. Another goal may be that the services have to be of high quality.

Although quality is the subject of this book, I want to make it clear at the outset that quality as an issue of health policy is subservient to the more important issues of effectiveness, efficiency and equity. There may be legitimate reasons for neglecting or postponing full commitment to quality – particularly if defined as scientific-technical quality – if it is felt that the more pressing issues have not been satisfactorily solved. It should also be emphasized, however, that the quality of health services is intricately intertwined with their other aspects and cannot easily be separated from them. It is also possible – and ethically mandatory – to aim at optimizing the quality of services within a given set of constraints, even when the highest priority is given to other considerations. As a consequence, quality is not a mere luxury that only the richest countries can afford, as has sometimes been claimed, but an integral part of all health services.

For the systematic study of these issues, several research methods are available. The determination of efficacy is the task of basic research; it has to demonstrate whether a new vaccine indeed prevents a disease, whether an operation prolongs the life expectancy of a patient, or whether a test increases the probability of a correct diagnosis. Clinical research assisted by health services research can help to assess the effectiveness of services. Cochrane (*1*) has strongly argued that all treatment and diagnostic methods should be scrutinized as to their effectiveness, and has advocated the use of randomized controlled clinical trials as the most powerful tool. The determination of efficiency is typically a task for health services research, more specifically for economic appraisal. Whether equity has been achieved can be measured by means of epidemiology and utilization studies. The assessment of the quality of the services, finally, falls under quality assurance, the main topic of this report. As a research methodology, quality assurance belongs to the domain of health services research.

This publication combines two elements: a policy- and methodology-oriented discussion on the choices one has to make in developing and analysing a quality assurance scheme; and concrete examples taken from the European quality assurance scene. The examples stem from visits made to several European countries as part of a study launched in 1977 by the WHO Regional Office for Europe. The following countries were selected on the basis of prior knowledge by either the Regional Office or the author about persons interested in, or activities concerned with, quality assurance:

Belgium
Czechoslovakia
Denmark
Finland
France
German Democratic Republic
Germany, Federal Republic of
Greece
Hungary
Iceland
Ireland
Italy
Netherlands
Norway
Poland
Portugal
Spain
Sweden
USSR
United Kingdom
Yugoslavia

The data were collected by interviewing representatives of national health authorities, professional organizations, and research and educational institutions. A simplified version of the conceptual framework described in chapter 1 was used to structure the interviews. Special attention was paid to the focus, sponsorship and motivation of quality assurance activities. The aim was not to conduct an objective comparative study but to provide concrete illustrations of the more theoretical issues. If an issue could have been illustrated by means of several examples, I have chosen that which, in my opinion, best makes the point or on which I have most information. This approach may disappoint those who would like to find detailed accounts of various programmes and compare them, but is more relevant to the aim of providing a background for informed discussion, and it certainly corresponds much better with the degree of precision of the data.

The book comprises three distinct parts. In chapters 1–3 a conceptual framework for the development and analysis of any quality assurance programme is suggested. This framework purports to identify and describe all the major variables and their attributes that can be used to describe systematically quality assurance activities. The framework is based on ideas and concepts derived from two sources – evaluative research and industrial quality control – because it is felt that, for the purposes of quality assurance, health care can best be conceived of as a production process and that quality assurance, in turn, is an example of evaluative research.

The second part (chapter 4) deals with methodological issues. Sources of information, types of care to be assessed, sampling, the selection of criteria and standards of good care, and the methodological properties of the measuring instrument are mentioned as problems requiring special consideration. Available methods are described with, it is hoped, sufficient details to give an idea of their possible applicability without, however, going into an unduly detailed methodological discussion.

The last section (chapter 5) contains conclusions concerning the "state of the art" of quality assurance in Europe.

In all sections, special attention is paid to conceptual, political and ethical considerations. Value judgements have, however, been avoided unless the empirical evidence seems to justify them. This emphasis is based on the notion that for any country, institution or person considering the implementation of a quality assurance programme, it is vital to take a stand on the controversial issues. Literature describing the actual methods and experts capable of providing consultation aid can be found easily once the policy-related problems have been solved.

The book ends with a selected but, it is hoped, rather representative reference list, which should help an interested reader to find the material most relevant to his needs. Although a special effort has been made to cover European literature, the great majority of the references are American, since by far the longest tradition of quality assurance is found in the United States. For language reasons, the extensive literature in Russian has not been included. Some of the literature referred to contains excellent bibliographies; the reader may particularly wish to consult those in references *2-9*.

1

Conceptual framework of quality assurance

Classification of the existing, but at times confusing, wealth of material pertaining to quality-related research and quality assurance presumes a conceptual framework which lists all the variables and their attributes that can be used to describe systematically such activities. In the elaboration of this framework, two notions can be used.

1. Quality-related research and quality assurance as evaluation.
2. Health care as a production process.

The first provides the substance of the framework, the second the theoretical basis for its application in health care.[a]

QUALITY ASSURANCE AS EVALUATION

Quality assurance is basically an evaluative activity. In evaluation, it is customary to distinguish among three components pertaining to the programme, activity or service under scrutiny: the environment, the conceptualization, and the methodology.[b]

The environment consists of the sociopolitical structure of the society, the existing and pending legislation concerning the programme and related programmes, and the attitudinal environment. In the case of the quality assurance of health services, the pertinent environmental factors are naturally the health care system and health legislation. Conceptualization comprises the explicit definition and implementation of the objectives, the target population, the corrective measures to be used, the time axis, the expected effects of the activity, etc. The methodology consists of the development and use of a measuring instrument. As a part of the methodology, such properties of the measuring instrument as sensitivity, reliability and validity have to be ascertained.

---

[a] In the literature, rather general frameworks for quality assurance can be found in Donabedian (*4-6*) and Greene (*7*) and somewhat more limited ones in Brook et al. (*2*) and Jacobs et al. (*8*).

[b] For an extensive treatment of evaluation, the interested reader may consult references *10-18*.

THE FRAMEWORK

The following outline of a conceptual framework aims at listing the major variables used to describe quality-related activities and at identifying the most important attributes of these variables.

Environment

1. Motivation
    - ethical motives
    - safety motives
    - economic motives
    - educational motives
    - punitive motives
2. Sponsoring agency
    - health professionals
    - consumers
    - organization (state, insurance company, etc.)
3. Strategies to influence quality
    - standard-setting
    - basic and continuing education
    - quality assurance programmes
4. Locus of quality assurance
    - primary/secondary/tertiary care
    - ambulatory/inpatient care

Conceptualization

1. Quality
    - effectiveness
    - efficiency
    - adequacy
    - scientific-technical quality
2. Objectives of quality-related research
    - "pure" research; fact-finding; problem identification
    - screening for poor performances and performers

- policy planning and programme evaluation
- guarantee of minimum standards; regulation
- improvement of quality
- consumer protection

3. Focus of quality-related research
   - structure of health services
   - the production process of health services
   - the end results of health services

4. Time perspective
   - retrospective activities
   - prospective activities
   - concurrent activities

Methodology

1. Source of information
   - records
   - forms
   - routine statistics
   - participatory observation
   - consumers' opinions
   - providers' opinions
   - psychometric and other indirect sources

2. Unit of analysis
   - provider/groups of providers/types of provider
   - institution/groups of institutions/types of institution
   - unit of service/types of service
   - care given by a provider, etc.
   - care given in an institution, etc.
   - care given in the case of a given diagnosis/group of diagnoses
   - care given in the case of a given operation/type of operation
   - care received by a consumer

3. Sampling
   - total coverage
   - partial coverage/sample

4. Criteria of good care
   - specificity: general *v.* disease-specific
   - type of criteria: ideal *v.* empirical
   - explicitness: implicit *v.* explicit

5. Standards of good care
   - methods of standard-setting: textbooks, experts, prevailing practices, etc.
   - types of standard: ideal *v.* empirical
6. Sensitivity of the measuring instrument
7. Validity of the measuring instrument
   - face validity
   - construct validity
   - predictive validity
8. Reliability
   - precision
   - reproducibility
   - constancy

USES OF THE FRAMEWORK

The suggested framework is by no means complete. Some of the variables are more fundamental than others and will determine which attributes the others can take. For instance, if the time perspective is concurrent, only the production process can be assessed, and the use of the consumer's opinion as a criterion of quality limits the unit of analysis to the care given by a provider. Another limitation is that the attributes are, in many cases, not mutually exclusive. For instance, general and disease-specific criteria of good care can be used side by side, and a quality assurance scheme may aim both at screening for poor performance and at policy planning. As a consequence, the resulting classifications are not ideal in the sense that each quality assurance activity or scheme could be put in just one box and that there would be a box for each activity. These limitations notwithstanding, the framework should be helpful both in planning new activities and in classifying and describing existing ones.

In planning, the framework can be used as a check list. In classifying activities, the most convenient approach may be to develop various matrices. The number of the variables permits the construction of very complicated multidimensional matrices which may confuse rather than clarify. In most cases it should, however, be possible to single out two or three of the most important variables and develop a matrix that illustrates the logical possibilities. This can be illustrated by the following two examples.

1. Let us assume that a researcher is interested in knowing whether the quality assurance programmes sponsored by various agencies differ with regard to the component of quality on which they focus. He identifies three sponsors – consumers, providers and health authorities; and four foci – effectiveness, efficiency, adequacy and scientific-technical quality. His empirical data consist of the distribution of a number of programmes sponsored by these three bodies

according to their focus. The hypothetical results are shown in Table 1. In this case, the resulting matrix is simply a cross-tabulation. By various typographical means, our researcher may also illustrate the "interest profile" of various sponsors (Table 2).

2. Let us now turn to a planner who wants to visualize how the time axis should be taken into account in various activities defined by their objectives and focus. In Table 3, he has used objectives and focus as his horizontal and vertical axes, respectively. The text in the intersection indicates whether the activity should be retrospective, prospective or concurrent with regard to the health services whose quality is being scrutinized. The blank spaces indicate illogical or inapplicable combinations of objective and focus.

A few comments may further clarify this idea. Let us look first at the empty spaces. By definition, a programme evaluation is concerned with achieving the objectives of the programme. Consequently, the focus of programme evaluation has to be the end result. Preferably, the research design should be prospective, but often one has to be content with a retrospective evaluation. Consumer protection in the sense used here aims at protecting the patient from treatment errors; it therefore concerns the process and has to be concurrent to be effective. "Pure" research (such as that aiming to clarify the concept of quality) is the most versatile; it can focus on structure, process or end result and can be retrospective or prospective. Screening for poor performance concerns process and can only be concurrent or retrospective.

In the following sections some of the more important variables of the framework will be discussed in detail, but first the production of health services will be compared with the production process in general.

Table 1. The focus of interest of quality assurance programmes sponsored by different agencies

Component of quality that interests the sponsoring agency	Sponsoring agency		
	Consumers of health services (N = 42)	Providers of health services (N = 60)	Health authorities (N = 36)
Effectiveness	30%	20%	5%
Efficiency	5%	8%	60%
Adequacy	50%	7%	30%
Quality	15%	65%	5%

Table 2. The interest profile of agencies sponsoring quality assurance

Component of quality that interests the sponsoring agency	Sponsoring agency		
	Consumers of health services	Providers of health services	Health authorities
Effectiveness	▨	▓	□
Efficiency	□	□	▦
Adequacy	▦	□	▨
Quality	▓	▦	□

Legend: A given component of quality is:

□ of virtually no interest to the sponsoring agency

▓ of some interest to the sponsoring agency

▨ of moderate interest to the sponsoring agency

▦ of high interest to the sponsoring agency

HEALTH CARE AS A PRODUCTION PROCESS

Many of the ideas and some methods that are being used in the quality-related research of health services closely resemble those used in industrial quality control, and have in some cases been derived from industrial methods.

Quality control in industry

Quality control originated in industry as a passive control: the customer who bought a deficient product was compensated for any loss. In its earliest form,

Table 3. The appropriate time perspective in quality assurance programmes with different objectives and foci

Focus of the quality assurance programme	Objective of the quality assurance programme			
	Programme evaluation	Consumer protection	"Pure" research	Screening for fraud
Structure			retrospective or prospective	
Process		concurrent	retrospective or prospective	concurrent or retrospective
End result	prospective or retrospective		retrospective or prospective	

the checking of quality was left to the customer, to be carried out at or after the time of purchase. This approach was primarily concerned with the economic consequences of poor quality; it did not in any way prevent dissatisfaction and irritation caused by the deficient product and the inconvenience related to obtaining compensation. The analogy in health care would be malpractice litigation. Gradually, industry itself assumed the responsibility for checking the quality of products before they reached the market. This was, however, still basically a passive approach to securing quality products.

The next stage was the introduction of active quality control. This consists of checking both the raw material and the entire production process at critical points so as to prevent the occurrence of deficient products, an approach analogous to modern quality assurance in health care. This development has greatly benefited from improved sampling techniques, statistical methods and automated data processing. Industrial quality control has also been very quick to apply advances in cybernetics.

The original concept of quality control was concerned with the quality of the product. The methods, while applicable to big industry, were not applicable to the production of services, or of commodities in which the amounts produced were small and frequently changed. As some form of quality control was deemed desirable in such types of production as well, the methods were modified so as to focus on the process of production instead of the product.

Industrial quality control can be conceived of as consisting of a flow of information parallel to the production process:

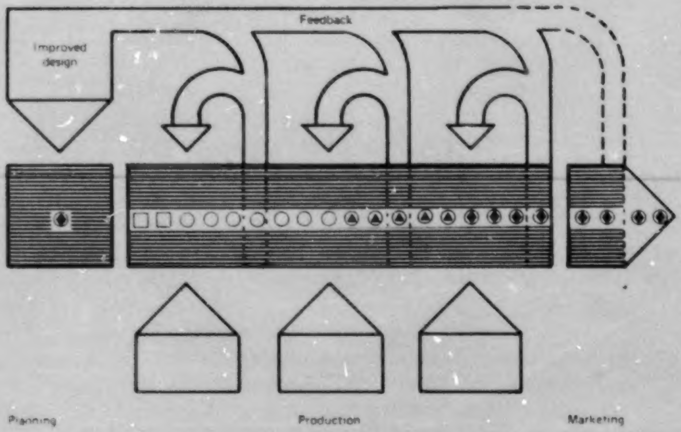
(*a*) obtaining information from the production;

(*b*) comparing this information with the qualitative requirements established for the production; and

(*c*) influencing the production process on the basis of the information obtained in the previous phases.

The critical points from which information is collected cover the entire production process, as well as planning and marketing. Fig. 1 illustrates this concept of quality control.

Fig. 1. Quality control of industrial production



By using several checkpoints, it is possible to finely tune the process on the basis of the information provided by the control mechanism. This diminishes the number of deficient products that will reach the final control – that of the market. In general, the more refined the product, the more important the role of planning, i.e. the centre of gravity of quality control shifts from the production line to the planning department. The plan has to incorporate all the features that guarantee that the product will be suitable for its intended purpose, acceptable to the consumer, and easy to produce. This idea is crystallized in the old saying that quality cannot be inspected into a product – it has to be built in.

Health care as production

Many health professionals find it hard to think of health care in terms of production, but that is what health care is from the economic point of view – production of health services. When a patient enters the health care system, he triggers a production process that should fit his needs as closely as possible. In spite of this individuality, however, it is possible to identify certain more or less invariable basic components of the process: typically the "production line" of patient care consists of history taking, diagnosis, treatment (including rehabilitation) and follow-up. The actual content of these components depends on the patient and his needs, the health personnel, the institution where the patient [illegible] being treated, etc. Fig. 2 illustrates this production process and quality control in relation to it.

This model starts with the assumption that the health care system provides certain preconditions for producing health services. These preconditions constitute the structure of the system and include the personnel, facilities and equipment. These structural elements can be assessed in terms of pre-established qualitative criteria. The actual production process consists of tasks carried out by various categories of health personnel working in various facilities such as private offices, group practices and hospitals, and in various parts of these facilities, such as outpatient departments, wards, laboratories, X-ray departments and intensive care units. For these tasks, qualitative criteria can be developed. They may be either general or disease (problem)-specific, and they may vary according to the facility where the tasks are being performed.

Finally, each episode of care has some outcome or end result. Although the prognosis is a traditional part of care, health professionals are not particularly accustomed to setting forth expected outcomes. It is possible, however, to state such outcomes for certain problems and to compare the actual outcomes with the expected outcomes.

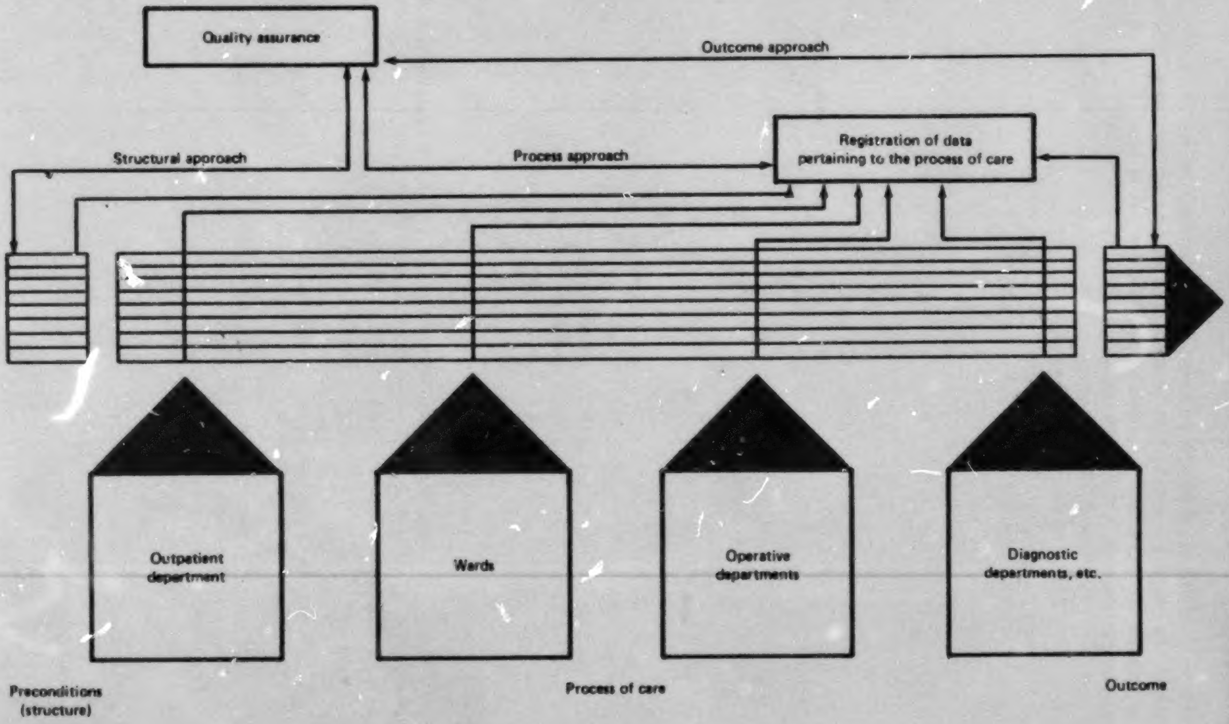
Analogy between industry and health care

The idea of comparing health care to industrial production may be appalling to many health professionals. It is, however, completely legitimate and educative, and is being increasingly accepted. Duncan (*19*) has the following to say in his review of quality assurance in the United Kingdom:

> If you walk round an automated factory you come at the end of each stage to a section clearly marked "quality control station". It is high technology and automation that have led to the need for quality control in industry. The role of the doctor in society has been overtaken by high technology and by teamwork. The technological part of modern medicine is more amenable to audit and quality control than are personal relationships and the caring and communication roles of the health care team . . . It would be defeatist to limit audit to the technological aspects of care.

Clearly, the analogy with industry is not perfect. In industry, the raw material is usually rather homogeneous, and consequently a small sample suffices to indicate its quality. Should it be deficient, the entire lot can be discarded. As the product is usually composed of several parts, a deficient part can be changed or corrected without any permanent damage to the rest of the product. If needed, the product can be disassembled or broken up so as to identify the cause of deficiencies and to prevent the same problem

Fig. 2. Quality assurance in health care: three basic approaches


Quality assurance
Outcome approach
Structural approach
Process approach
Registration of data pertaining to the process of care
Outpatient department
Wards
Operative departments
Diagnostic departments, etc.
Preconditions (structure)
Process of care
Outcome

from recurring. The entire production lot usually undergoes the same treatment, and therefore occasional probes may suffice to detect problems in production. Finally, and most importantly, the producer may suffer financially should he be forced to discard a deficient product, but since the product is normally one of a great number of similar products and can thus be replaced, usually no party experiences any permanent or irreparable damage.

In health care the "raw material" consists of patients. These are certainly not homogeneous, and patients with a poor prognosis (i.e. poor raw material) also have to be treated. Each patient requires an individual package of health services; only the "containers" (i.e. the components of the care) remain the same. Should something go wrong, the production line cannot usually be stopped and a sample taken for detailed analysis. Especially in critical cases, the treatment has to go on and a new course of action selected before the results of any fault-finding are available. It is not only the production process that has to be kept running smoothly, but every single product counts. Failures can be irreparable, and the system bears full responsibility. The main difference between quality control in industry and in health care lies perhaps in the dual – and consequently more complex – objectives of quality control of health care; whereas the objective in industry is primarily to prevent the occurrence of deficient products in the future, quality control in health care aims both at prevention and at guaranteeing for every patient safe, good quality care.

In spite of these differences, certain lessons can be learned from this analogy. First, the example of industrial quality control has demonstrated that even highly individualized production, such as that of services or of small lots of individual articles by craftsmen, can be subjected to control. This presumes that the focus be shifted from the product to the process. In health care, this implies that the process of care has to be divided into identifiable components, and these in turn to tasks for which qualitative criteria can be established. This exercise is valid, however, only if the relation of these tasks to the outcome of the care can be determined. Consequently, research on the health care process should be intensified.

Second, the more complex the product the more important it is for quality control to be introduced at the planning stage. Transferred to health care, this does not mean that the structure of the health care system should be made the focus of quality control, but that the effectiveness of the services be ascertained before their incorporation into the arsenal of health care. As Brook (*20*) has remarked, once the application of a certain measure has become a part of "conventional wisdom", it may be almost impossible to subject this measure to randomized controlled trials or other studies to determine its effectiveness. Such attempts are often considered to be unethical because the patients are being denied something that conventional wisdom holds valuable.

Third, the feedback principle is equally as important in health care as in industry, and is reflected in the terminology used. *Quality assessment* refers to the determination of the actual level of quality of a system or a service. It is a methodological concept, whereas *quality assurance* is an action-oriented concept based on feedback and with clear policy connotations. Quality assurance comprises the actual measurement and the ensuing measures to modify the production of the health services in the desired way (i.e. feedback). Quality assurance always has a policy objective – the improvement of quality. Most often, this improvement is considered to consist of the raising of the scientific-technical level of care. However, if one accepts the relevance of the concepts of optimum quality and logical quality, the improvement may also mean the lowering of the scientific-technical level of care or the elimination of certain services.[a]

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[a] Quality control, patient care evaluation, peer review and medical audit have sometimes been used as synonyms of quality assurance. The word "control" has unpleasant connotations for many people. "Medical audit" should be reserved for the retrospective analysis of the quality of care on the basis of medical records. "Patient care evaluation" omits the remedial aspects of the activity, as does the term "peer review", which also limits the activity to the peers – perhaps desirable but not necessarily true. Therefore, the relatively neutral term "quality assurance", which refers to the objectives rather than to the process of the activity, is usually preferred in health care.

2

The environment of quality assurance

The environment of quality assurance can be examined from two viewpoints: (*a*) the environment of the health care system in its broadest sense, i.e. all the factors that influence the quality of the production of health services and its outcomes; and (*b*) the environment of the quality assurance process *per se*, i.e. the legal, political, professional and social values, norms and attitudes that govern such an activity.

Donabedian (*21*) has suggested that an individual's health can be influenced by the medical care system, genetics, the environment and the patient's behaviour. Blum (*22*) has elaborated a basically similar but even larger notion of the determinants of the outcome of health care. He emphasizes that the level of health of the people is only to a very modest degree the result of health care. Also, Roemer (*23*) draws attention to the broad array of factors influencing health. According to Roemer the following preconditions should exist to maximize the impact of health care: a safe and hygienic environment, an educated population, an adequate supply of physical and human resources, financial access to medical care, geographic accessibility, and a continuing flow of new knowledge.

The level of health in the population is the ultimate criterion of the effectiveness and quality of the health care. The level of health is, however, determined by a great variety of factors, the majority of which fall outside the health care system. Consequently, the health care system can be held accountable only for such variation in the level of health as is caused by variables capable of being controlled or manipulated by that system. Quality assurance deals only with these variables. It is the task of other forms of quality-related research and of health services research in general to measure such determinants of the level of health that are outside the immediate domain of the health care system but belong to its environment.

With regard to the normative and attitudinal environment of quality assurance, perhaps the most important issue is whether the quality assurance is mandatory or voluntary. In most industrialized countries there is some form of mandatory control with regard to the structure of health care, whereas the process and outcome approaches have been largely left to professional initiative. Some outcomes, however, such as maternal and infant deaths, are considered to be so important that they are subjected to mandatory scrutiny. Certain important procedural controls, such as tissue committees and determining the accuracy of laboratory tests, may also be mandatory even though there is no systematic quality assurance.

MOTIVATION OF QUALITY ASSURANCE

Quality assurance is needed because health care – like all human activities – is characterized by variation: we have both poor and high quality care. Variation increases as the health care system becomes more complex. All qualitative and quantitative increments in the resources available for the production of health services are likely to increase such variation. Thus, the more numerous and varied the categories of health personnel, the more numerous and sophisticated the apparatus, and the more pronounced the hierarchy of health care institutions, the more variation there will be. Quality assurance aims at ascertaining the magnitude and causes of this variation and at changing it in a desired fashion.

The specific motives of quality assurance can be placed in three broad categories – ethical, safety, and efficiency motives. In addition, educational and punitive motives have sometimes been advanced as separate categories, but these seem either to fall under the three main headings or can be considered means to change quality rather than motives. The desire to punish a wrongdoer should, in any case, play a very minor role in quality assurance; punitive actions should be the last resort in attempts to improve the quality of care, applied only in cases of gross deficiency and flagrant violation of established norms.

In most European countries there is a vaguely expressed interest in the quality of health services, and relatively few have provided motivation for such an interest. The socialist countries are an exception; in most of these, the constitution or other law guarantees every citizen's right to health. From this broad principle more specific guidelines and objectives can be derived, although the qualitative objectives are often very general or refer only to the type and scope of activities rather than to their quality. For instance in Hungary, besides the reduction of mortality in early childhood and in middle-aged men, continuity of care and equity are given as qualitative objectives. Qualitative objectives may also concern organization. Thus in Czechoslovakia, the law provides for qualitative objectives regarding the organization of care: all health services should be integrated and regionalized.

Apart from this general interest, however, specific quality assurance mechanisms are rare in Europe, since many factors that have given rise to systematic quality assurance in the United States are not considered a problem. There have, in fact, been warnings against unquestioning importation of purely American approaches to quality assurance (*24*). There are several reasons. Most European countries are relatively small – at least in comparison with the United States. Many of them have a fair degree of central planning and control. The medical schools may be under the control of state authorities and there are relatively few of them. The majority of health care institutions are public or at least publicly subsidized. Salary is a common – in many countries the only – form of remuneration.

The result of all these factors is a relatively small amount of variation in the health care institutions, in the education of the providers, and in the actual provision of health services. The salary system alleviates or completely suppresses some of the untoward consequences, such as unnecessary services, claimed to be caused by other remuneration mechanisms, particularly by the fee-for-service system. When there is variation, its reasons are often easy to pinpoint. In addition, the national health authorities have a handle on the system: they can use the central planning mechanism to reduce original variation and the subsidy system to foster conformity when undue variation occurs. Despite these considerations, there seems to be a growing concern about quality, and an interest in systematic quality assurance.

After rising costs, variation is the second major factor that has given rise to discussion of quality. In many countries *ad hoc* or systematic studies have been conducted, revealing surprisingly large differences in such variables as the average length of stay, frequency of complications, and even mortality among hospitals with similar structures, resources, and types of patient.

Ethical motives

The Constitution of the World Health Organization embraces the principle that everyone has the right to the highest attainable level of health. This seems to imply that everyone also has the right to the best possible health care. The emphasis should, however, be on the word "possible" and the principle could perhaps be rephrased to read that everyone has the right to optimum care. This principle, then, states the ethical motivation of quality assurance in its broadest sense. In some countries this principle has been embodied in the constitution or other legislation. According to Rosenthal (*25*), the fact that the consumption of health services is considered a social value automatically implies an ethical obligation to ascertain the quality of these services as well as their availability.

The monopolistic nature of the production of health services underscores the importance of ethical considerations. Especially in countries with nationalized health care systems there is little or no competition between the providers, be they institutions or individuals. Consumers may not be in a position to choose between different providers, and they are usually ignorant of the quality of the services they receive. All these factors enhance the moral and ethical responsibility of the providers to maintain high quality.

Health professionals, and especially members of the medical profession, are – like members of all professions with a sophisticated body of knowledge and a high level of technical expertise – also naturally interested in working at a high qualitative level and in constantly improving the quality of their work. This attitude, in fact, is part of the ethos of the profession. Professionalism, however, may be at odds with the development of quality assurance programmes. The professionals claim that their work is simply not amenable to quality assessment, let alone to any kind of control (*26*). Even when they accept the idea of measuring the quality of their work, professionals may claim that they are the only ones who can establish qualitative criteria and standards and who can study the performance of their peers. However, the consumer is also responsible for demanding high quality services because, in the last analysis, it is his ignorance and indifference that allow poor quality services to exist.

Safety motives

In health care the stakes are high – sometimes the life of the patient. This explains the long-standing interest in ways of guaranteeing at least a minimum quality of facilities, equipment and personnel. The oldest quality assurance methods, such as the licensure of health personnel and the accreditation of facilities, aim at securing a minimum standard. Quality assurance methods based on safety motives are usually the first to be introduced in any country, and those most readily comprehended and accepted by all parties concerned.

The educational value of quality assurance is commonly acknowledged by all those involved – you learn from your performance, including the mistakes. This learning possibility is closely related to safety. One of the main objectives of professional education is to equip providers with such skills and knowledge that will render them useful to the client and prevent them from being harmful. One of the oldest ethical norms of the medical profession is *primum non nocere* (first, do no harm). Consequently, it is often the educational value of systematic quality assurance that persuades health professionals to accept it. They have been instrumental in shifting the focus from mere assessment (i.e. measurement) of quality to quality assurance. Assessment provides the necessary information for planning of interventions to improve quality. Basic and especially continuing education is a central strategy in transforming the methodology-oriented assessment into policy-oriented assurance.

Efficiency motives

Two trends in medicine itself have drawn attention to the quality of health services: increasing effectiveness and rising costs. As long as the relative share of health care in the national economy was limited and medicine was not particularly effective – a situation that can be said to have existed up to the First World War – it was, from an economic and societal point of view, not very important to know the quality of the health services. Economically these services were marginal and, since their overall effectiveness was low, it did not make any great difference whether their quality was good or bad, provided that clearly injurious practices could be prevented. In this kind of situation, minimum quality safeguards were sufficient. However in the new situation ushered in by medical progress, where many services are very expensive, highly effective and can have disastrous consequences if applied unskilfully, it becomes exceedingly important to ensure that scarce resources are used to produce services that are not only efficient (i.e. costs are small in relation to effects) but also meet a high standard of scientific-technical quality. Efficiency and scientific-technical quality may, at times, be at variance with each other, since attempts to maximize the latter may reduce the former. Decision-makers and administrators often stress efficiency, while providers and consumers are more concerned with scientific-technical quality. There is, however, clearly an increasing emphasis on identifying the optimal – as explicitly opposed to the maximal – qualitative level of care and on maximizing quality so as to increase efficiency.

SPONSORING AGENCIES

The three most important sponsors of quality assurance are national health authorities, professional bodies, and individual professionals and scholars. Although there are clear signs that bodies representing the consumers are becoming more and more interested in the quality of health services, their role in actively promoting systematic quality assurance has been negligible. Health insurance systems also play a relatively limited role; their interest is usually economically motivated and often focuses on screening for fraud and overutilization of services.

In Europe, particularly, the health authorities have a virtual monopoly in setting of standards for health care institutions. They may also be in a similar position with regard to educational standards, although this may be the prerogative of the professional societies or universities as well. The same applies to the licensing of health personnel. Health professionals are often responsible for quality assurance activities in health care institutions. Health professionals, especially those working in academic settings, have sometimes pioneered experimentation with new methods. Often, however, professionals are either uninterested in or downright hostile to quality assurance in these institutions. They justify their stand by referring to the assumed small variation in the quality of care.

Self-defence may, however, induce them to take an interest (*27*). What lies behind their fears is beautifully illustrated by the following passage from *The Times* of 8 September 1978: "... in parts of the profession at least there is a feeling that something must be done. That something might be an extended form of peer review or medical audit. In peer review a doctor's own colleagues review cases so that lessons can be learnt. Whether doctors move fast enough to satisfy public and parliamentary pressure or whether Parliament will decide it cannot wait long enough for doctors to put their house in order ... are questions still to be answered" (quoted by Duncan, *19*). However, even in the face of this possible encroachment upon the professional turf, medical opinion may remain opposed to systematic quality assurance: "We are not convinced of the need for further supervision of a qualified doctor's standard of care" (submission of evidence by the British Medical Association to the Royal Commission on the National Health Service, 1977). In this context, attention is drawn to an increasing number of arrangements that indirectly improve the quality of care: professional promotion based on merit, seniority payments, continuing education, group practice, and the use of local hospitals and general practices for teaching medical students and graduate trainees (which may both increase the relevance of medical training to the needs of the population and the quality consciousness of the practitioners working in such settings). Hospital doctors claim that every ward round with colleagues and trainees amounts to quality control (*19*).

In discussing the sponsoring agency, it is important to remember the informal structures and social processes that influence a physician's practice patterns. Rhee et al. (*28*) have noted that too often the design of regulatory mechanisms such as quality assurance focuses on the intricacies of formal administrative structure and fails to give proper consideration to the workings of such informal processes. Their empirical data suggest that the care received by patients treated by more colleague-dependent (in terms of referrals) physicians tended to be of higher quality. These findings could be taken into account by providing incentives to encourage the formalization of otherwise informal relationships (e.g. promotion of more organized forms of practice and stronger medical staff organization in hospitals) and by tying the formal control mechanisms to the informal processes of control.

There is no doubt that the attitudinal environment is rather rapidly becoming more favourable to quality assurance due to various pressures and interests. There is not enough experience for generalizations, but one might predict that the sequence of events could be as follows: the original initiative comes from the professional ranks but is being resisted by the health professions as an unnecessary and unjustified intrusion into their work. At this initial stage, the health authorities remain rather uninterested. Gradually, however, it is the health authorities who, because of rising costs and a genuine interest in the improvement of the quality of care, assume the leadership, encouraging research and experimentation and finally introducing legislation. At this stage, the health professionals try to recapture the initiative and embark upon developing the necessary methodology and shaping the content of the activities so as to correspond with their interests. This may result in an emphasis on the educational value of quality assurance as opposed to the economic emphasis often characteristic of the activities launched by the health authorities.

STRATEGIES TO INFLUENCE THE QUALITY OF HEALTH SERVICES

In the broadest sense, a strategy is any method employed to improve the quality of care, regardless of whether the quality has been measured or not. In a more narrow sense, a strategy is the last component in the quality assessment-quality assurance sequence, which consists of the following components:

(*a*) *approach:* the particular aspect of care (structure, process or outcome) to be assessed;

(*b*) *technique:* the method used in the measurement of the quality;

(*c*) *strategy:* the method used in the correction of the discrepancies between the observed and desired level of quality.

Thus the approach sets the stage, the technique is the methodological component, and the strategy is a health-policy-related device that converts assessment into assurance. All components entail important choices: which approach, which technique, and which strategy.

The environment of quality assurance usually limits the choice of strategy. The available and politically feasible alternatives are determined by the prevailing political and social attitudes and existing legislation. In some countries only persuasion and education are possible; in others coercion may be feasible.

The strategies are not always clearly formulated and may consist of various nonspecific suggestions to improve care, which Blum (*22*) has called the "more and better" approach:

- do more research
- do more technological development
- require higher levels of training and qualifications for all health personnel
- require higher levels of continuing education, retraining, re-examination and recertification
- provide higher rewards for conforming
- threaten more severe penalties for not conforming
- check more often and more thoroughly to see that everything is at its best

As such suggestions are not related to any specific objectives of care and are not derived from any measurements of the degree of accordance between observed and expected performance, they are only very remotely related to quality assurance.

Roemer (*23*) has suggested that the main strategies ("social mechanisms of control" to use his terminology) be the following:

- setting of standards for personnel
- creating organizational frameworks conducive to high quality
- health planning
- regionalization
- control of drugs and appliances
- disciplinary incentives

If one thinks of corrective measures to be implemented in the case of an individual provider of services, after assessment of the care provided by him, only three strategies seem feasible:

(*a*) educational measures such as refresher courses, continuing education and re-examination;

(*b*) organizational measures such as reallocation of tasks, reorganization of the physical environment and the provision of certain resources or facilities; and

(*c*) disciplinary incentives such as promotion or demotion following the results of quality assessment, and pecuniary incentives or disincentives.

Because education, particularly continuing education, has often been claimed to be the most important strategy for improving the quality of health services, it will be discussed under a separate heading. However, some of Roemer's points that will not be discussed later deserve a comment here. It should be noted that many of them are used independently of any systematic quality assessment in attempts to create the prerequisites for high quality care.

Regionalization. Health planning may ultimately be the most important vehicle for improving the quality of care. Regionalization can be considered either an objective or a method of health planning. Its aim is to make optimum use of scarce resources by developing a hierarchical system of health services and health institutions responsible for a defined area or population, each having the most appropriate personnel and equipment for the task at hand. It seeks to prevent duplication of activities and equipment. By concentrating certain activities in certain places, regionalization can ensure that the skills of health workers will not get "rusty" from lack of patients. Regionalization is particularly relevant for the achievement of optimal quality.

Organizational frameworks. This strategy is closely related to health planning. Opinions differ as to the real impact of the growing size and complexity of modern health care on the quality of services produced. On the one hand, it has been claimed that complex mammoth organizations will result in bureaucracy, inefficiency, job dissatisfaction on the part of the staff and alienation on the part of the patients. On the other hand, complex organizations may have their own mechanisms for maintaining quality by delegating tasks, dividing responsibilities, establishing specific quality assurance mechanisms, etc. The small size of an institution can also be a source of poor quality, for instance by making it difficult to achieve economies of scale. Although hard data are lacking, it is commonly felt that the construction of very large hospitals was a mistake and the trend is back towards institutions with "humane" dimensions. When organizational changes are explicitly used to improve quality, they are primarily related to the structural approach to quality assurance, and their objective is to create an environment that fosters high quality and consumer and provider satisfaction.

Control of drugs and appliances. In the past, such control was primarily concerned with the safety of the drugs and appliances. There is, however, an emerging trend to require producers to demonstrate the effectiveness of their products. Furthermore, in some countries the health authorities, the insurance companies, or the medical profession may monitor the actual prescription patterns of individual physicians. Deviations from the average pattern can thus be analysed. Motivation for such monitoring is primarily economic, and only secondarily related to safety. The introduction of computer-based information systems has increased the possibility of checking the appropriateness of the prescription and identifying such eventualities as potentially dangerous interactions of prescribed drugs, overdoses and allergic reactions before the drug is dispensed. Such a system is one of the most typical examples of concurrent consumer protection.

Education as a strategy for improving the quality of health services[a]

Education is related to the quality of health services in four ways.

1. Education as a guarantee of quality: basic education aims at guaranteeing that one of the major components of the health care system – health personnel – has the potential to produce high quality services.

2. Education as a remedy for poor quality: continuing education is one of the most common means of rectifying the situation once qualitative deficiencies in the provision of the health services have been detected.

3. Education of the consumers: the public has to be educated to distinguish between high and poor quality and to use the available services properly.

4. Education of the providers: the providers have to be educated to accept quality assurance, to use the results of quality assessment, and to perform such assessments themselves.

In spite of this four-fold role in quality assurance, the importance of education seems to have been exaggerated. Although the literature pertaining to quality assurance is replete with such statements as "quality continuing education is a major mechanism for maintaining competence" (*30*), a score of authors have maintained that lack of knowledge is by no means the only – not even the most important – cause of poor quality. Jessee & Goran (*31*) suggest that the majority of problems of poor quality are problems of organization and administration rather than lack of knowledge. The types of problems, and their possible solutions, suggested by Jacobs et al. (*8*) (Table 4) and by Morehead & Donaldson (*32*) (Table 5) illustrate this point.

Even in knowledge-related problems, education is not always the solution. When the knowledge has never been learned, education obviously helps; if the knowledge has been learned but its use is obstructed, further education is difficult. Attempts to teach something that is already known may be very frustrating and create motivational barriers. In a Delphi project on continuing education (*33*) the majority of participants felt that the most important objective of continuing education was to translate existing knowledge into medical practice, not to impart new knowledge.

The starting level and amount of variation in the quality of services are often overlooked when offering education as a solution to qualitative problems. The lower the starting level and the more variation there is, the more efficient education will be as a remedy. To take an extreme example, a modest rise in the educational level of indigenous midwives in a developing country

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[a] This section draws heavily on material by the author previously published elsewhere (*29*), by kind permission of Elsevier Scientific Publishing Company, Amsterdam.

Table 4. Causes of quality-related problems and types of remedial action

Cause of problem	Type of remedial action
Lack of knowledge or skill	Education – new techniques or procedures – update or refresher
Lack of feedback	Information system – one time (e.g. results of audit) – continuous reports
Environmental barriers	Organizational and administrative changes – division of labour and delegation of tasks – new or relocated equipment, supplies or personnel – new or revised policies
Attitudes	Education, incentives, sanctions

can result in spectacular improvements in the quality of maternal and child health services. Such an educational strategy is also likely to be very cost-effective. In an industrialized country, one should be very cautious when recommending wholesale educational approaches to raise the quality of care. However, in a large country with numerous medical schools and a non-centralized system, education may be an effective means of improving quality, especially if directed at clearly defined target groups. In a small country with central planning and control, a clear hierarchy of health care institutions, and uniform standards for personnel and education, organizational measures may yield the greatest benefits.

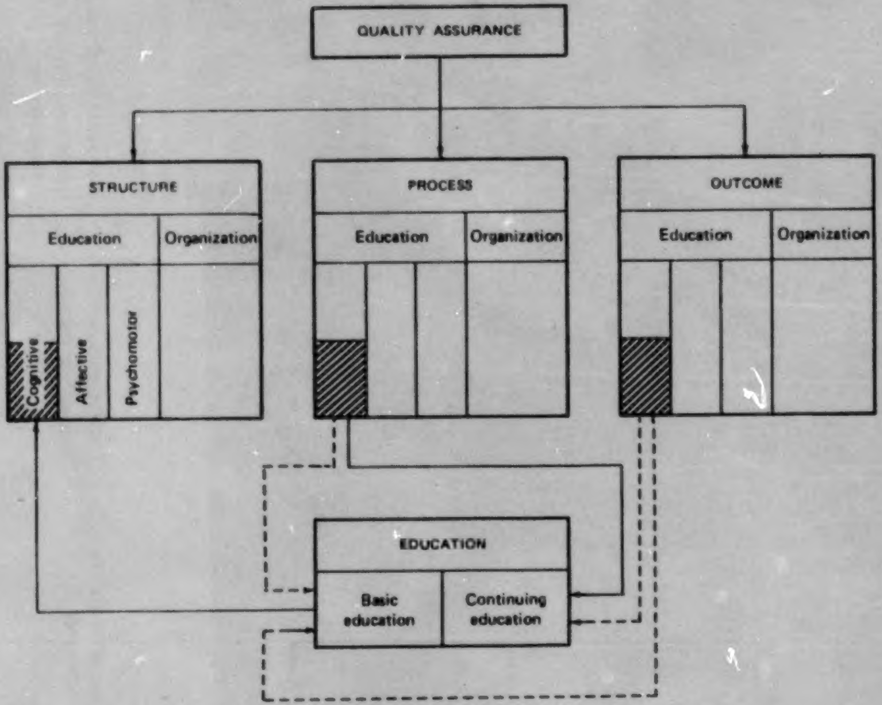
On the basis of the previous discussion, a view of the role of education as a strategy to improve the quality of health services emerges (Fig. 3).

Education is related to each of three basic approaches to quality assurance (structure, process and outcome, see p. 56) but not to the extent often assumed. The basic limitations are as follows: (*a*) only a part – probably less than half – of qualitative deficiencies in the production of health services are primarily educational (i.e. lack of knowledge, skills and attitudes), the rest are organizational; (*b*) only a part of the basically educational problems can be solved by means of individual-oriented education, the rest are due to obstructions to the use of knowledge or skills; and (*c*) most quality-related educational programmes concern only cognitive deficiencies, leaving affective aspects and psychomotor skills aside.

Table 5. Causes of unsatisfactory care and types of remedial action

Cause of problem	Related causes	Type of remedial action
Lack of systems	High broken appointment rates	Procedural manuals
	High drop-in rates	Designation of responsibility and supervision
Delay in instituting diagnostic procedures	Lack of continuity	Medical audits
Lack of patient follow-up	Physician turnover	Organized medical record problem list
		Review of reports prior to filing
		Special identification of patients with diagnostic problems or chronic disease
Lack of adequate hospital relationships	Teaching hospital restrictions	Centre physician participation in hospital services including time for educational/service commitments
	Poor data flow	Contractual arrangements
		Liaison office at hospital
		Improvement of data collection on centre patients
Poor physician performance	Professional isolation	Standards for physicians
	Inadequate training	Continuing educational programmes
		Defined role for consultants
Poor patient compliance	Social pathology	Patient counselling (exit interviews)
	Poverty	Home assessments
	Lack of understanding	Follow-up by community workers

Fig. 3. The role of education in quality assurance


QUALITY ASSURANCE
STRUCTURE
Education
Organization
Cognitive
Affective
Psychomotor
PROCESS
Education
Organization
OUTCOME
Education
Organization
EDUCATION
Basic education
Continuing education

Basic education is primarily related to the structural approach. The direction of the arrow in Fig. 3 indicates that basic education is an *ex ante* guarantee that a part of the structure – the training of the personnel – meets established standards. The dotted arrows coming from the process and outcome approaches indicate that sometimes, albeit seldom, basic education can be revised on the basis of the assessment of the quality of services.

Continuing education is usually an *ex post* remedy once either the process or outcome approach has revealed deficiencies. The outcome approach almost invariably leads to an analysis of the process or structure to find out the reasons for the deficiencies and thus the most appropriate remedial actions.

THE LOCUS OF QUALITY ASSURANCE

In principle all health services should be subjected to quality assurance; in practice most programmes concern hospital care. The reasons for this limitation are related to the nature of hospital care and to the relative ease with which the quality of hospital care can be assessed in comparison with care provided in other settings. As a discrete administrative unit, a hospital is also a convenient unit for analysis. Hospitals may have clearly defined service areas and target populations; their activities may also be more clearly defined than in ambulatory care. This especially applies to countries with a regionalized, hierarchical hospital system. Hospital care comprises the most expensive part of health services, and consequently its quality may have far-reaching economic effects. A hospital is also a conspicuous element of the health care system, much more so than the rather amorphous primary care and, as such, naturally attracts the attention of decision-makers as well as consumers.

Christoffel & Loewenthal (*3*) mention the following advantages connected with quality assurance in hospitals.

1. Because hospitalization normally continues until the severe stage of illness and disability has passed, it is possible to pinpoint an intermediate patient outcome in the form of the discharge status. This allows the outcome approach to quality assurance, as opposed to a mere structural or process approach.

2. In hospitals, the corrective part of the quality assurance is easy to implement. Hospitals often have continuing education programmes to which the findings of quality assessment can be geared (*34*).

3. As a quality assurance programme reaches a great number of physicians in hospitals, the efficiency of such programmes in terms of disseminating knowledge about quality assurance and creating a propitious atmosphere is greater in hospital than in ambulatory care. Hospital-based programmes may thus have a kind of "snowball effect".

4. It should also be noted that the quality of hospital records is usually far superior to that of records in ambulatory care.

5. Finally, as the hospital often serves as an educational centre for the surrounding area, it has been assumed that the quality of hospital care provides a measure of the quality of care produced within its catchment area (*35*). However, the opposite view has been advanced: general practice and general practitioners are the factors common to all specialties and have a bird's-eye view of the whole range of health and welfare services, and should thus have priority in developing quality assurance (*36*). Even within hospitals there has been a tendency to limit the scope and focus of quality assurance. The bulk of quality-related literature pertains to surgical and medical care because of their assumed great socioeconomic significance and methodological ease.

Quality assurance in primary care

Gradually, primary care has gained increasing attention as a subject of quality assurance. It has been noted that any enterprise with the dimensions of primary care is bound to control its own effectiveness and efficiency and that primary care is conspicuous because of a dearth of knowledge about the production process and the quality of the product (*27*). It has also been claimed that primary care is of such importance for the entire health care system that its quality has an overwhelming influence on the quality of that system (*37*). Evaluation of the quality of care provided in ambulatory and primary care is, however, beset with many problems that pertain both to the nature of care and the methodology to be used.

The basic problem is that there is much more to primary care than correctly diagnosing and treating a disease. Primary care must deal with what the patient is experiencing, not only with what he "has", i.e. primary care is more concerned with people than with diagnoses, diseases and life-threatening events (*38–40*). Doney (*41*) has summed up this problem as follows: "If it is difficult to audit the care of diseases, will it ever be possible to audit the care of patients?" The special nature of the medical encounters in primary care makes it necessary to develop measurements suitable for this sector of care. Applying standards that have been developed for the assessment of hospital care may result in the risk that the essential features of primary care will be ignored, since such standards usually only pertain to a limited number of organic diseases – which certainly do not represent the whole spectrum of conditions seen in primary care (*42*). Christoffel & Loewenthal (*3*) have summarized the difficulties in assessing the quality of ambulatory and primary care as follows.

1. There is no easily definable episode of illness in ambulatory care; chronic diseases particularly pose problems in this respect.

2. Outpatients are less likely than hospital patients to receive a specific diagnosis.

3. Outpatient records are not uniform and are seldom complete.

4. There is no history of quality-orientated activities in ambulatory settings, whereas in hospitals such activities date back to the beginning of this century.

5. The physician has less control over the ambulatory patient's adherence to instructions or a prescribed regimen than over the hospital patient.

6. There is a considerable range in the severity of diseases and conditions treated on an ambulatory basis. This raises the question of whether all care should be evaluated or whether quality assurance programmes should focus on the more severe illnesses, in which case an effective screening or sampling mechanism is needed.

7. There are significant differences among ambulatory care facilities. Conversely, the fact that hospital care is more standardized facilitates the construction of norms and the setting of standards.

In addition lack of clerical help, time, suitable organization and, perhaps most important, of a tradition of research in primary health care have been major handicaps.

The task of evaluation in primary care is thus formidable. In its broadest sense, it should cover assessment of the achievement of objectives, which have been suggested (*43*) to be the following:

(*a*) to provide medical care that is accessible to the whole population of the country;

(*b*) to provide care that is acceptable to the population;

(*c*) to provide a system of care capable of identifying those medical needs of the population that can be prevented, modified or satisfied by therapeutic intervention; and

(*d*) to provide a system of care that can use to the maximum the available manpower and financial resources to meet the medical needs of the population.

The Declaration of Alma-Ata, the basis of WHO's current approach to primary health care (*44*), broadens these objectives even more. As Vuori (*45*) has noted, current information systems contain virtually no indicators that could be used to monitor our progress towards the largely qualitative objectives of the Declaration. An entirely new data base, data capturing mechanism and set of indicators will be needed to measure such parameters as consumer participation, patient satisfaction, affordability, and contribution to overall socioeconomic development.

Even if one limits the task to assessing the quality of primary care services, it still remains formidable. Mushlin & Appel (*39*) have summarized it lucidly: quality assurance in primary care should focus on the success with which medical care assists patients in resolving their health problems; in doing so, attention to technical competence is necessary, but techniques of assessing the technical process of care, especially when based only on data derived from medical records, can provide at best only a partial evaluation of the quality of care; outpatients share the responsibility for many aspects of the process of care, such as completing diagnostic tests or following medication regimens. Documentation of these aspects of the process of care is rarely found in medical records. Furthermore, determination of whether or not the diagnosis was correct and treatment effective frequently requires gathering information from the patient. An appropriate focus for evaluating ambulatory care, then, is the success achieved in alleviating the discomfort, disability and distress patients experience.

Expansion of the locus and focus of quality assurance

In spite of the tendency to limit quality assurance to the care of hospital patients with problems primarily in the fields of internal medicine and surgery, the scope and focus of quality assurance have broadened. Increasingly, care within other medical specialties is being assessed, such as psychiatry (*46*), paediatrics (*47*), gynaecology (*48*), and dentistry (*49*). Even the prescribing patterns of physicians have been evaluated (*50*).

The most important expansion of quality assurance has, however, been towards primary care. The two classics in this field are the studies by Peterson et al. (*51*) and Clute (*52*). A similar classic concerning care provided by group practices is the study by Daily & Morehead (*53*). If one accepts the notion that a congress, review articles and a journal are the signs of maturity in a discipline, quality assurance in primary care seems to have come of age, even though the journal is still missing. As early as 1974 the Royal College of General Practitioners, supported by the Rockefeller Foundation, convened a small international meeting to discuss ways of improving the quality of primary care (*37*). The American Society of Internal Medicine followed suit two years later by organizing a conference on the assessment of physician performance in ambulatory care (*54*). Reviewers both in the United States (*3*) and in Europe (*9,40,55*) have found ample material to review. Currently, interest in primary care seems to be particularly lively in Europe; for instance the President of the Royal College of General Practitioners has strongly advocated quality assurance (*56*). In the United States, too, it is fairly commonly believed that "there is now abundant evidence for the feasibility of performance review in the ambulatory care setting" (*57*).

In addition to the application of quality assurance methods, a host of other studies have yielded data on the quality of primary care. Such studies include activity analyses in primary care or general practice, investigations on critical incidents (e.g. death, iatrogenic complications and delays in diagnosis and instigation of care), morbidity surveys (which have revealed, for instance, differences between the observed distribution of diagnoses in a given practice and that expected on the basis of average distribution), facility analyses, accessibility surveys and time-and-motion studies. (For literature references see, for example, Mourin (*55*) and Duncan (*19*).)

A common finding in studies dealing with primary care has been that it offers a singularly suitable and challenging field for testing the inclusion of psychosocial variables in quality assurance. Primary care physicians have the knowledge and experience to provide needed expertise in the development of methods to evaluate the "art of care". Such evaluation is likely to have many benefits. Not only will it increase physicians' awareness of psychosocial issues, but it may also promote a comprehensive approach to health care leading to more satisfying outcomes for both physicians and patients (*42,58*).

One limitation of most studies is that they only concern the care provided by physicians. Moreover, studies on chronic, geriatric and terminal care, as well as prevention, are conspicuous by their absence. Donabedian (*21*) suggests that those segments of care that are most in need of scrutiny are the least likely to be subjected to it. In his view, formal quality assurance mechanisms are most needed, and most difficult to institute, in situations where the practice is poorly organized. Another grey area is the interface between primary and secondary care dealing with such aspects as patient referral and information transfer. The "trajectory" method of Brook & Stevenson (*59*) can be used to bridge this gap as it allows for tracking a group of patients through a delivery system, providing evidence of where breakdowns in the system occur and some indications of responsibility. For such breakdowns, the method also seeks to explore linkage between process and outcome within both the diagnostic and the therapeutic stages of care (*60*). The study by Gruer et al. (*61*) on the care of patients with acute abdominal pain is a European example of attempts to tackle this grey area.

3

The concept of quality

THE QUALITY OF HEALTH SERVICES

From the literature on quality assurance, three principal ways to define the "quality of health services" seem to emerge: nominal definition, content analysis, and operational definition.

The nominal definition is perhaps the most ambitious approach, as it aims at an all-embracing, logically coherent definition. So far, the results have not satisfied those in search of a need for such a definition. Many of them have agreed with Klein et al. (*62*) that there will probably never be a single comprehensive criterion by which to measure the quality of patient care, and have turned their attention to content analysis. In this approach, quality is conceived of as a many-faceted phenomenon with definable and measurable components. The lists of components of quality suggested by a WHO study group (*63*) and the American Public Health Association (APHA) (*64*) are typical examples. To the third group belong those pragmatists and sceptics who agree with Makover (*65*) that the term eludes a precise definition. In the time-honoured tradition of intelligence testing, they define quality by means of the method they advocate or use to measure it. The majority of empirical studies on quality seem to belong to this group.

Given the state of affairs of the day the definitions may, as Donabedian (*4*) has remarked, be almost anything anyone wishes them to be, although they ordinarily reflect the values and goals of the current medical care system and of the larger society of which it is part. It is therefore understandable that it has even been suggested that the whole concept of quality be discarded as too value-laden and as hindering rather than facilitating clear thinking (*66*).

It may be impossible to develop a definition that would satisfy all its users. As a consequence, every user of the concept should clearly spell out what he means by quality: quality for whom, quality defined by whom, quality for what purpose, and which aspect of quality. The most practical approach to doing this is perhaps the division of the concept into its components.

Components of quality

Let us start by reviewing some definitions suggested in the literature. The functional definition of quality used in industry provides a good starting point: quality is the capability of a product to fulfil its intended purpose, produced with the least possible cost (*67–69*). This definition suggests two important aspects of quality: (*a*) the fulfilment of the intended purpose of use and (*b*) relating the production costs to the degree of fulfilment. Using somewhat different terminology, point (*a*) can be equated with the *adequacy* of services (supply in relation to needs), and point (*b*) with *efficiency* (impact in relation to costs). The important point is the functional nature of this definition as opposed to a normative, ideal or maximum definition. The quality of a service or product may have an upper limit beyond which a further increase in quality becomes nonfunctional, or perhaps even dysfunctional, with regard to achieving the purpose for which the service or product is intended. For use expressly in health care, a WHO study group (*63*) suggested that the overall quality of health services be divided into three components: adequacy, efficiency and scientific-technical quality.

Starting from the premise that the fundamental goal of the medical care system is to make good medical care available to the population, APHA (*64*) has endeavoured to specify the meaning of "good medical care". The result is the following list of essential elements of good care.

1. Accessibility
    - personal accessibility
    - comprehensive services
    - quantitative adequacy
2. Quality
    - professional competence
    - personal acceptability
    - qualitative adequacy
3. Continuity
    - person-centred care
    - central source of care
    - coordinated services
4. Efficiency
    - equitable financing
    - adequate compensation
    - efficient administration

The category of "quality" in the APHA list is synonymous with the concept of "scientific-technical quality" suggested by the WHO study group. APHA also introduces two new important dimensions of "good care": consumer and provider satisfaction.

To summarize, in various contexts it has been suggested that quality-related research and activities can or should concern the following variables.

Effectiveness. The relation of the actual impact of a service or programme in an operating system to its full potential impact in an ideal situation.

Efficiency. The relation of the actual impact of a service or programme to its production costs.

Adequacy. The relation of available services to the needs of the population. This has a numerical component (the total amount of services in relation to need) and a distributional component (services available within regions and for population subgroups).

Scientific-technical quality. The level of application to care of the currently available medical knowledge and technology. This is the most common objective of quality assurance programmes. The term *quality* used alone without qualification almost invariably refers to this component.

Consumer and provider satisfaction. Consumer satisfaction with the services, providers and outcome of health care, and provider satisfaction with working conditions.

Accessibility. The possibility of a consumer obtaining the services he needs at a time and place where he needs them in sufficient amounts and at a reasonable cost. (This dimension, of course, is closely related to the distributional component of the adequacy of services and could conceptually be included in it.)

Continuity. The treatment of a patient as a whole person in an integrated way under the guidance of a central source of care. (If such attributes of services can be scientifically justified as characteristics of "high quality care", this component should be included under scientific-technical quality.)

I suggest that this list be simplified by placing accessibility under adequacy, and continuity and consumer satisfaction under scientific-technical quality. Provider satisfaction does not conceptually belong to this classification; while consumers are satisfied or dissatisfied with health services, providers are usually satisfied or dissatisfied with the system. It is, of course, entirely appropriate to speak of the quality of the system and provider satisfaction as one of the indicators of this quality, but not in this conceptual context. The resulting classification of the objects of quality-related research and activities is therefore as follows.

1. Effectiveness
2. Efficiency
3. Adequacy
4. Scientific-technical quality

Quality for whom?

In health care, depending on the system of the country, three or four concerned parties can be discerned: the consumers, the providers, the administrators, and the decision-makers. In some countries the interests of the providers and the administrators may be identical, in others those of the administrators and decision-makers may coalesce.

It is conceivable that the interests of these groups can be different, often even conflicting. In addition, the list of high-priority qualitative expectations or requirements of one group may vary according to the type of service or institution under scrutiny. Thus, there is both inter- and intra-group variation. As a consequence, in quality-related research, it is important to specify clearly who defines the criteria of good quality and to whom the benefits of high quality care are supposed to accrue.

The point is obvious if one examines the detailed list of the essential elements of good care suggested by APHA. For example, from the point of view of the consumers, satisfaction of the criteria "personal accessibility", "comprehensive services" and "quantitative adequacy" might presume a dense network of large and technologically sophisticated hospitals. Even for the consumers, these requirements may be at variance with their expectations concerning "person-centred care" and "coordinated services", let alone for administrators or decision-makers who will, in all likelihood, find such an arrangement administratively inefficient and economically wasteful.

It is commonly accepted that consumers' views on what constitutes high quality have been largely neglected. There is, however, an increasing awareness of the importance of these views among other groups, and growing pressure by consumers to make their views known and accepted. The problem, of course, is that the consumer's definition of good quality is perhaps the most nebulous of all. Some findings from the primarily sociological literature clearly demonstrate this. Elderly men seemed to consider the practical aspects of care as the decisive criteria of good quality, whereas elderly women emphasized the personality of the physician (*70*). According to Freidson (*71*) a good physician has to be interested in his patient and he has to be professionally competent. The organizational setting of the physician seemed, however, to influence how these criteria could be met – for example a group practice guaranteed technical competence but resulted in less satisfactory treatment from the emotional point of view. Hospital patients seemed to take high professional competence for granted and paid more attention to the psychosocial aspects of the doctor–patient relationship, whereas outpatients were more concerned with the scientific and technical level of the care they received (*72*).

The important point, however, is that patients do have their own criteria for good care, although these criteria may vary according to their demographic and socioeconomic characteristics or the type of institution in which they are treated and the kind of services they receive. Despite this variation, it has been demonstrated that quality ratings by patients have a relatively high degree of concordance with ratings obtained by other, more "objective" means (*73, 74*). It should be stressed that, as always in research, an explicit conceptual model and meticulously defined and valid implementation of the concepts help to overcome the difficulties posed by the variability of the phenomenon under scrutiny.[a]

Distribution of quality

In health care, statements such as "only the best is good enough for my patients" and "everyone is entitled to the best possible care" are common. Such statements contain, however, a logical error and a practical impossibility. The logical fallacy consists in ignoring the fact that quality is a continuous variable having some sort of a distribution. There are high and low quality parts to this distribution, and someone is bound to use the services offered at the low quality end. It is, of course, possible to try to push the entire distribution along the quality continuum towards higher quality or to compress it, and these are the aims of quality assurance, but it does not mean that everyone should be offered "the best" or that everyone is entitled to "the best".

The practical fallacy of such assertions is that there are economic limits to the improvement of quality. Brook et al. (*78*) have dramatized this latter fallacy by their fictional press release from 1999, according to which the US Congress passes a law that requires a physician to wear at all times a sign stating "I am dangerous to your health – beware". This law was passed as a result of the development that started with quality assurance activities in the 1970s. Because of the very stringent criteria established for high quality care, health care consumes over 50% of the gross national product and impairs the health of the population by causing iatrogenic diseases and by diminishing the amount of money people can use for the purchase of other commodities such as adequate food. Neuhauser & Lewicki (*79*) have illustrated the same problem by calculating the costs of an example of "high quality medicine". The American Cancer Society has endorsed a recommendation (*80*) according to which six sequential stool guaiac examinations be done on all persons over 40 years of age to detect silent colon cancer. Although an effective procedure, it is also a tremendously expensive one: the marginal cost of cancer detected at the sixth examination is over US $47 million.

Medicine is full of such well-meaning but economically unjustifiable recommendations and procedures that have been advanced to wave the banner of high quality medicine. It is frightening to think what the implementation of all such recommendations for all known patients would cost – let alone after all latent need for care has been detected by means of recommended screening and other procedures. In spite of this, many medical educators and representatives of the medical profession take pride in knowingly pushing aside all economic considerations.

Fig. 4, originally suggested by Greene (*7*) to describe the distribution of physicians in relation to quality, has been modified to illustrate the distribution issue in general.

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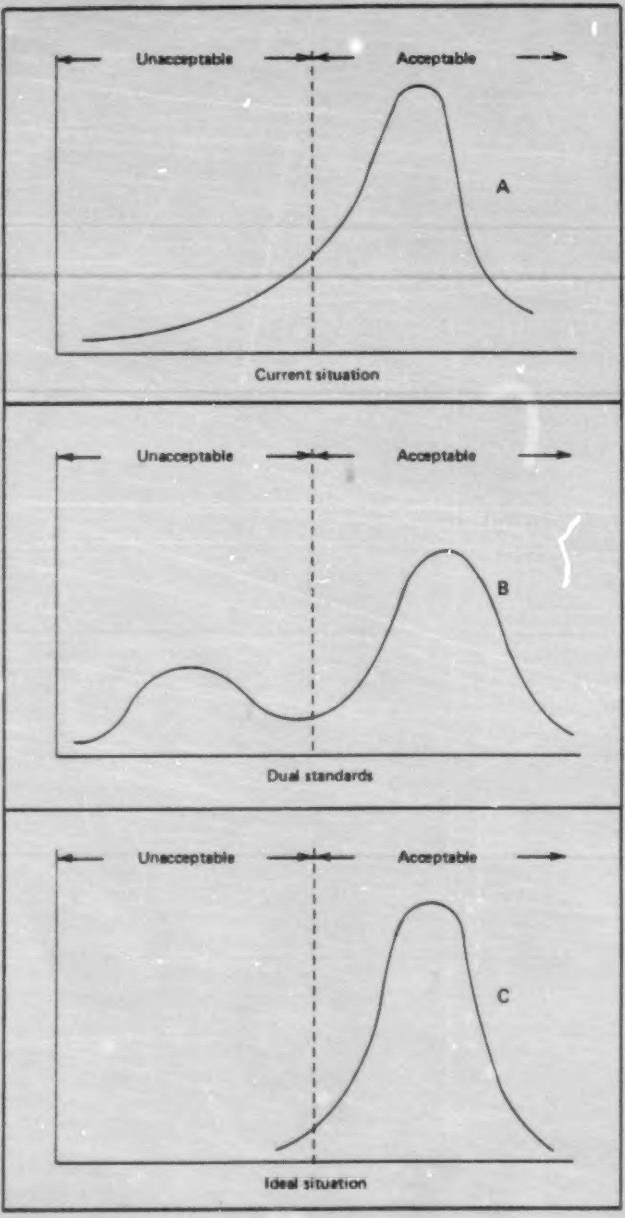
[a] For a standardized patient satisfaction scale see Zyzanski et al. (*75*) and for a general discussion on the implementation of patients' views see Starfield (*76, 77*).

Fig. 4. Distribution of the quality of health services



Curve A is perhaps the closest approximation to the current situation. The great majority of services are well above the cutting point between acceptable and unacceptable quality. There is, however, a relatively long tail of unacceptable services, whose quality has to be improved by means of quality assurance.

Curve B describes a situation where, for some reason, a double standard of care exists. This might be the case in some countries with an affluent minority consuming most of the high-standard services, and a socioeconomically deprived majority that has to rely on a limited supply of substandard services. The curve might also depict a situation where a sizeable part of the health services is being produced by traditional or unorthodox health providers, although it should be noted that the suggested shape of the curve in this situation results from the application of a professionally defined concept of quality.

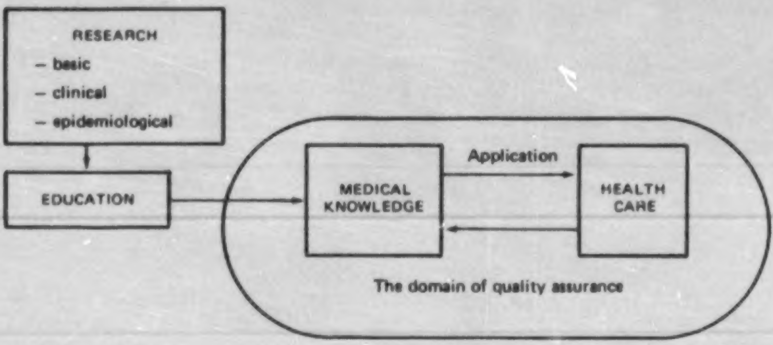
Curve C would be the ideal outcome of successful quality assurance: virtually all the services are of a high standard and the distribution is compressed, guaranteeing equity and eliminating unnecessary care.

The curves also suggest some of the uses of, and methodological issues connected with, quality assurance. Should the situation illustrated by curve B prevail, the objective of quality assurance would be primarily that of screening. A relatively simple methodology would suffice to find a cut-off point. As the extremes of the bimodal curve are readily identifiable, the sensitivity of the measurement is not a particular concern. In the case of curve A, quality assurance also aims at identifying substandard performances and performers, but the methodological problems are much more complicated; there is no natural cut-off point and it has to be agreed on. Consequently, the obligations related to measurement are much more stringent; the measuring instrument needs not only to be valid but also very sensitive and reliable so as to prevent social injustice to those on the borderline. There are also clear political overtones since one has to decide – not on the basis of any clear "scientific" evidence but on that of compromise or convention – not only the cut-off point but also the desirable location of the entire distribution to reach the ideal situation described by curve C. Once this "ideal" has been reached, the task of quality assurance is to maintain the achieved qualitative level and to detect fraud.

The preceding discussion has aimed at demonstrating that "the best care for all" is fiction; although the distribution of the quality of services can be pushed to the right and compressed, there will always be some variation. In addition, the quality of health services is a relative concept, the actual content of which very much depends on where, when and by whom it is being used. Besides these situational factors, the substance of the scientific-technical quality changes by definition: quality means the application of *currently available* medical knowledge and technology. At any given time, medical practitioners apply knowledge and technology that has been produced and validated and that education has transmitted to them (*81*). Slee (*82*) has illustrated this process (Fig. 5).

When medical knowledge changes as a result of research and becomes available for application by health professionals through education, the cut-off point between acceptable and unacceptable care changes as well. If there were a one-to-one relationship of research through knowledge to application, the entire quality distribution would accordingly move to the right. Legitimately, however,

Fig. 5. The relationships among research, education, health care, and quality assurance focusing on scientific-technical quality



it can be asked whether the distribution of scientific-technical quality should always be pushed towards higher quality irrespective of other considerations. These considerations give rise to the concept of optimal quality.

OPTIMAL QUALITY

The previous discussion identified the two most important reasons for treating the quality of health services as an optimization problem: quality means different things to different people, and its content varies according to situational and substance factors. The functional definition of quality used in industry is an example of the optimization approach. The following theoretical treatment of this problem draws on van Ettinger & Sittig (*69*) and Vuori.[a] The analysis is not limited to scientific-technical quality but takes account of all the components of quality presented above.

A health service (or an institution or a provider) can have several qualitative properties $c_1, c_2, \ldots, c_n$ (e.g. adequacy, effectiveness, efficiency, scientific-technical quality). The concerned parties (consumers, providers, administrators, decision-makers) weigh these properties differently. These weights can be expressed in the form of a coefficient assigned to each property (w_i).

Now the absolute utility (or value) of the service from the point of view of the party (i) is:

$$w_{i1}c_1 + w_{i2}c_2 + \ldots + w_{in}c_n$$

If the quality of health services were a maximization problem (i.e. "the best for all" approach) and the providers (i = q) were considered to be the legitimate sole definers of what constitutes good quality (as is often done), the solution of the equation for service (j) having qualitative properties c_k would be of the form:

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[a] Material by the author previously published elsewhere (*45*) is reproduced here by kind permission of J.B. Lippincott Company, Philadelphia.

$$\sum_{k=1}^{n} w_q c_{jk} \longrightarrow \max$$

However, the functional approach takes into account the cost of producing these services. Furthermore, the basic tenet of this approach is that the level of quality need not exceed that dictated by the objectives of the care. Therefore, the production costs (p) of the service should be deducted from the total value or utility of the service. If so desired, the costs can be weighted by the relative value (m) to the parties concerned of the resources needed for the production of the service. The real utility (v) of the service is thus:

$$v_{ij} = \sum_{k=1}^{n} (w_{ji} c_{jk} - m_i p_j)$$

where i is the party concerned (provider, consumer, administrator or decision-maker), j is the service, and k is the qualitative property (c) of the service.

Accordingly the value of all health services, taking into account the priorities of all the parties concerned, would be:

$$v_{ij} = \sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{k=1}^{n} (w_{ij} c_{jk} - m_i p_j)$$

This equation may have no practical use, as it is impossible to determine the magnitude of the elements that go into it. However, if one focuses on one service at a time, the practicability of the approach increases greatly. The costs of a service can be ascertained, the qualitative objectives can be stated, and social scientists have developed various ranking methods to determine the subjective weights assigned to the objectives.

In health economics, methods closely resembling that outlined above have been used in attempts to determine the relative economic value of various health programmes. The willingness-to-pay approach has been used to obtain the weights that should be assigned to the programmes to be compared.

Quality and costs

The utility equation for a service,

$$v_{ij} = \sum_{k=1}^{n} (w_{ji} c_{jk} - m_i p_j)$$

encapsulates the essential elements of the functional approach: quality has several components, they may be variously appreciated by the parties concerned, and the costs of the service are part of its quality. Even if the equation – for want of real figures – cannot be used in actual calculations, it helps to visualize the interdependence of these factors.

If we omit the factor $m_i p_j$ (the costs of the service weighted by the significance of the economic factors to the parties concerned), we get the "absolute utility" ("absolute quality") of the service. This is the situation, for instance, when the health services are free to the consumer. Since the marginal costs of a qualitative improvement in a service – and of a quantitative increase as well – are zero, consumers are likely to demand any qualitative or quantitative increments they are aware of and believe to benefit them, unless there are non-monetary constraints such as pain, inconvenience or time.

The same situation results when the provider for some reason omits the cost factor. This may happen for instance when, in medical education, no attention is paid to medical economics, or when ethics dictate that the professional should forget about such mundane things as costs and always provide the best that medicine can offer. There may also be organizational settings that blind physicians to the cost constraints. Teaching hospitals and research centres operating with liberal grants may foster an inattentive attitude to cost. Also, certain types of health insurance may be conducive to extravagancy with regard to quality and quantity.

The natural result of a lack of cost-consciousness is that both the consumers and the providers push for the maximum quality of services. This attitude, which prevails in many countries, has certainly been one of the causes of the cost explosion in health care, and it also inevitably creates conflict among consumers, providers, administrators and decision-makers. The two latter groups simply cannot afford the luxury of closing their eyes to the cost of unnecessarily high quality. There have been innumerable battles where physicians have defended the acquisition of some new gadget, waving the banners of "quality" and "safety", against administrators who have requested a demonstration of effectiveness and efficiency.

Rosenthal (*25*) has maintained that improvement in the scientific-technical quality of health services always means a trade-off with some other valued aspect of health care, usually resulting in either increased costs or reduced services. Although in most cases this is certainly true, it is quite conceivable that there could be qualitative differences in an equal amount of services produced with equal resources. This ostensible paradox is explained by the fact that one of the most important causes of qualitatively deficient care is an improper attitude – not so much lack of knowledge or failure to use some sophisticated apparatus (*34*).

Selection of the optimal qualitative level

In the production of commodities and services, selection of the optimal level of quality of the products is one of the most difficult problems. By now, it should have become clear that, in the production of health services too, the most appropriate qualitative level is not a maximization but an optimization problem. The factors that determine the optimal qualitative level are the production costs of the services and the benefits obtained. Let us first look at the resulting relationships between these factors, viz. quality *v.* production costs and benefits (utility) *v.* quality.

Quality v. costs

Quality – especially if defined as scientific-technical quality – can be bought. Lewis (*83*) has suggested that there are three different relationships between quality and costs: (*a*) a linear and positive association – increased costs result in improved quality, which has real functional utility in relation to the objectives of care; (*b*) a scatter diagram – increased costs result in ostensibly better care, i.e., in more numerous and sophisticated services which, however, have no functional utility; and (*c*) a quadratic curve. I suggest that the third alternative comes closest to the truth.

The relationship between quality and costs probably follows an "inverted U" distribution, as shown in Fig. 6 (*78*). In the beginning, the qualitative improvements are relatively cheap but gradually their marginal costs increase up to a point after which added resources may actually lower the quality. This lowering results, for instance, from poor communication and cooperation among more and more providers, from iatrogenic risks associated with the use of increasingly sophisticated technology, and from inconvenience and time loss for the clients.

Benefits (utility) v. quality

The relationship between benefits obtained (utility) and quality behaves somewhat differently (Fig. 7). Very poor quality may lead, for example, to iatrogenic problems, loss of confidence in the health care system, and delays

Fig. 6. The costs of improving quality

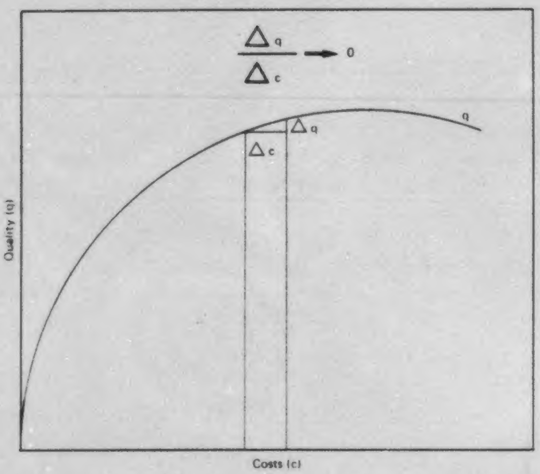
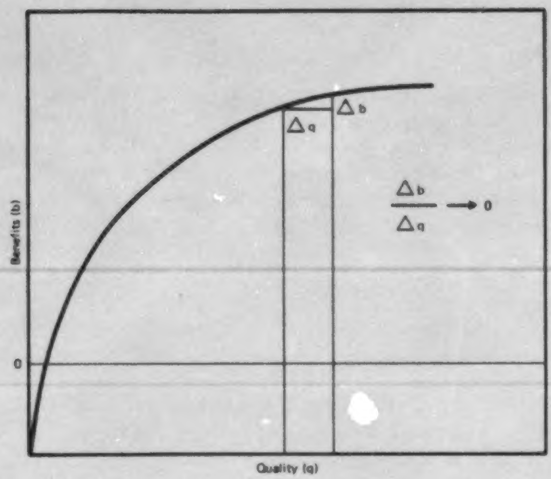


Fig. 7. Utility of services as a function of their quality



in seeking care. When quality improves, a point is reached after which modest increments in quality yield great benefits. This situation prevails for instance in the developing countries, where dramatic improvements in the health of the population can be inexpensively bought – provided that the resources are wisely invested. Gradually, the law of diminishing returns becomes operative, i.e. the marginal utility of the service decreases more and more for each successive increment in quality. For instance, the marginal utility of increasing the certainty of a diagnosis from, say, 70% to 90% by deploying more diagnostic tests may be great, whereas an increase from, say, 90% to 95% may be sheer luxury since it does not change the therapy in any way.

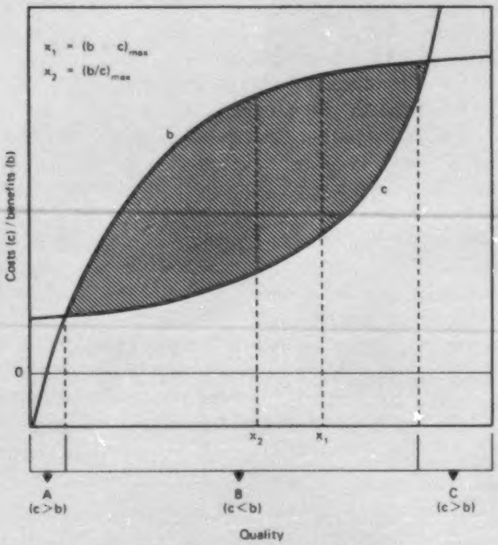
The costs and benefits of improved quality

Fig. 8, which presents both production costs and benefits (utility) as a function of the qualitative level of services, summarizes the previous discussion. In Fig. 8 there are three interesting areas. Within area A costs exceed utility for two reasons: there are costs associated with "zero quality" production, and the utility of such production may even be negative. Within area C the marginal costs exceed the marginal benefits of qualitative improvements. Economically, it is feasible to produce services only within the shaded area, i.e. as long as benefits (utility) exceed production costs. Within this area there are two points at which the cost-benefit relationship is optimum:

$$b - c \longrightarrow \max \quad (x_1)$$

$$\frac{b}{c} \longrightarrow \max \quad (x_2)$$

Fig. 8. The benefits and costs of production as a function of the qualitative level of services



The greatest difference between the utility and the costs of a product (x_1) always occurs at a higher qualitative level than the maximum cost-benefit ratio (x_2). Consumers would prefer to set the qualitative level at point x_1 since they either want the maximum benefit for their money or a given benefit at the lowest cost. From the producer's point of view, however, point x_2 represents optimal quality as it makes the most efficient use of available resources.

This difference in looking at the optimal quality of production may result in tension between providers and consumers. Generally, consumers have a tendency to push for a higher level of quality than providers. In this respect, health care differs from most sectors of production. Health professionals may join the consumer in pushing for higher than optimum quality. This is especially true if they are not private entrepreneurs but work in or for a system that helps them forget about costs. By resorting to arguments such as the development of medical science, the safety of the patient and the nature of health care, they deny the validity of the concept of optimal quality.

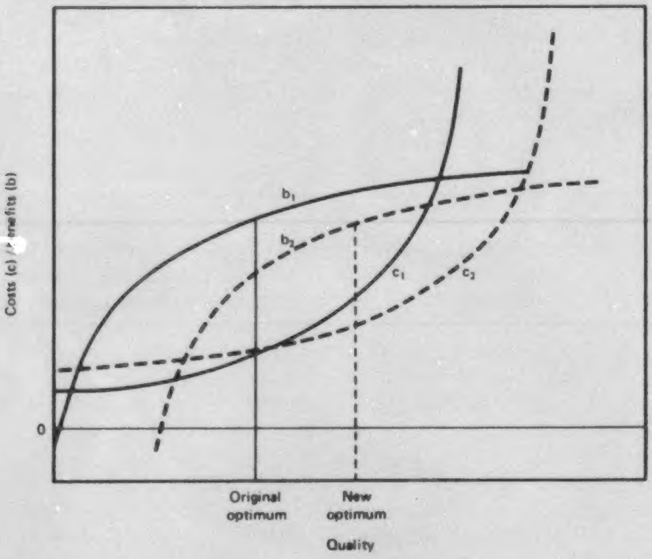
In summary, from an economic point of view, it is possible to define an area within which the quality of a health service should lie. This is the area where marginal utility exceeds marginal costs. The blurring of the cost issue because of free or heavily subsidized services and professional ethics may result in a situation where health services are being produced at a qualitative level which is well beyond the optimum point both for the system $(b(x)/c(x) \longrightarrow \max)$ and even for the consumer $(b(x) - c(x) \longrightarrow \max)$.

The optimal qualitative level is a changing one. The curve describing benefits as a function of quality may be moved to the right by medical and technological progress. Because new procedures or apparatus may yield new benefits, working at the old optimal level may be considered substandard. Correspondingly, new production techniques and better organization can enable providers to maintain the same quality at lower cost. In Fig. 9 the broken lines (b_2 and c_2) describe the new situation which also results in a new qualitative optimum at a higher level (*69*).

This analysis does not, of course, purport to maintain that high quality, health insurance and other systems of subsidy, or a highly developed professional code of ethics, are undesirable. It must be emphasized, however, that the concept of an optimum level of quality should be accepted as a useful analytical tool in discussing the quality of health services, and that the cost of improved quality should not be forgotten.

There is an increasing recognition of the importance of the relationships among quality, costs and utility. The most tangible examples are the efforts made in many countries with different economic and political systems to regionalize health services and to create a hierarchical system of

Fig. 9. The changing benefits and production costs as a result of medical and technological progress and new production techniques



health institutions. In such systems, there is an implicit or explicit recognition of the fact that the content of "the best health care" depends on the circumstances. In other words, quality is a relative concept.

LOGICAL QUALITY

Donabedian (*4*) may have been the first to use the concept of logical quality. If one accepts the concept of optimal quality, the concept of logical quality actually becomes superfluous. It deserves, however, a separate treatment because it pertains to very salient issues in health policy. It is derived from information theory and refers to the efficiency with which information is used in arriving at a decision. The first issue is whether the information obtained is relevant or irrelevant for the decision to be made; the second consists in the use of the relevant information. There may be duplication in obtaining it, because it has been overlooked in the first instance, or the amount of information collected may exceed the requirements of decision-making in the situation at hand.

Poor logical quality is one of the reasons why the qualitative level of health care is not always optimal. As most of the resultant issues have already been dealt with in connexion with optimal quality, it suffices to point out just a few problems specially related to logical quality. Poor logical quality increases the costs of care because information gathering is one of the most expensive components of care. Unnecessary information may also be downright injurious. It creates disturbing "noise" in the decision-making system that may hamper the proper utilization and interpretation of the necessary information and cause random errors (*84,85*). Many quality assurance programmes lower the logical quality of care by establishing unnecessary and irrelevant criteria. A great number of procedures that are considered to be a part of "good care" are performed to increase the probability of a diagnosis being correct from, say, 95% to 97% – very often with no concomitant changes in treatment.

Logical quality is most applicable in the process approach but is relevant to the structural approach as well. For instance, a typical criterion for acceptable or good structure is the educational level and competence of the personnel. Because in many countries salaries constitute over 70% of health care costs, the way in which personnel are used is not a trivial matter. The use of over-competent personnel certainly lowers the logical quality of care and increases its costs.

Reasons for poor logical quality

The Constitution of the World Health Organization contains the principle that everyone has the right to the best attainable health. This implies that everyone also has the right to the best possible health care, as health care is generally considered to be the most important means of improving health. The monopolistic nature of the production of health services underscores the importance of this principle. In health care, there is often relatively little competition among providers, especially in countries with a national health system. The consumers are therefore not in a position to choose between different providers; they are usually also ignorant of the quality of the services they receive. All these factors enhance the moral and ethical responsibility of the providers to maintain a high quality of service. I do not want to argue with this principle, which is one of the cornerstones of medical ethics, but I would like to rephrase it to read that everyone has the right to optimal care, i.e. to the best care in relation to the objectives of care.

In health care there is an inherent and understandable tendency towards low logical quality, i.e. too much information. Health care is characterized by uncertainty. To reduce this uncertainty, professional and societal norms have been developed. One of the most deeply rooted of these norms is that a physician commits a much greater error if he determines a sick person to be healthy than if he treats a healthy person as if he were sick (for a discussion of this decision-making model see Scheff, *86*). This norm seems to be based on two questionable assumptions: (*a*) a disease is a deterministic phenomenon with serious consequences unless the health care system intervenes, and (*b*) the personal and social consequences of becoming labelled as sick and of being treated are trivial. The corollaries of this norm for logical quality are obvious. First, a person seeking a physician's help will, for safety's sake, be labelled as sick, and then subjected to extensive diagnostic procedures and tentative or definitive treatment so as to be absolutely certain that the sin of letting a sick person go untreated has not been committed. In many countries alarming trends in malpractice litigation have enhanced the physician's inclination to "play it safe".

This emphasis on logical quality does not purport to suggest that health personnel should lower standards of work across the board and resort to guesswork and superficial diagnostic procedures. It aims at underlining the importance of an adequate task analysis and the delegation of tasks on the basis of educational level when determining the optimum personnel structure of an institution or of the entire health care system. It is also designed to remind one that, when defining the criteria of "good care" and when measuring the "quality of care" using these criteria, one should analyse and explicitly state whether the criteria really are essential or whether they are just a part of defensive practice or designed to satisfy prestige or professional pride. Finally, it should be evident that often more use can be made of existing information. This suggests that considerable gains could be made by paying more attention to decision-making and information theory in the education of health professionals.

OPTIMIZING THE YIELD OF QUALITY ASSURANCE

The idea of choices among alternatives to achieve an optimal result is becoming more and more popular in health policy, and can be extended to quality assurance as well. The objective of quality assurance is to measure the actual level of quality and to identify and implement appropriate remedial actions. The "pay-off" of quality assurance can thus be increased by choosing the correct services and components of quality to be assessed, proper measurement methods, and effective remedial actions.

Locally set priorities are an obvious possibility for increasing the cost-benefit ratio of quality assurance, as they focus attention on areas that are perceived to be problematic. Williamson et al. (*87*) have strongly emphasized the importance of setting priorities. Before assessment and improvement efforts can be undertaken, target areas have to be selected where quality assurance will have the greatest impact on health and costs. In studying the priorities for quality assurance in eight health care facilities, they found that most areas of health impact potential, as perceived by local professional staff, were highly individualistic. Not one topic was mentioned by the staff of all eight facilities. Should an assessment reveal qualitative deficiencies, one could expect a high level of motivation to adopt the suggested corrective actions, if the setting of priorities has been done by or in cooperation with those whose activities are being scrutinized.

There seems to be a consensus that the two basic components of quality assessment are the quality of the technical care (scientific-technical quality) and the quality of the art-of-care, i.e. the milieu, manner and behaviour of providers in delivering care to and communicating with patients. The overall quality of care can be improved by raising the level of these components either one at a time or together. So far, quality assurance programmes have almost exclusively been concerned with scientific-technical quality, although there may be more need and possibilities for improvement on the side of the art-of-care – especially if one wants to take the qualitative expectations of the consumer into account. The present trend is towards improving the technical aspects of care, which will most certainly not produce the largest increments in health for a given amount of money. It is necessary, however, to solve the ethical problems related to many measures intended to improve the quality of the art-of-care and to compare their cost-benefit ratio with that of measures aiming at improving the scientific-technical level of care in spite of the assumed superiority of the former.

In another context (*29*) I have suggested that current remedial actions to correct observed deficiencies in the quality of care have been overly dominated by educational measures. There are, however, three basic limitations to the use of educational measures in quality assurance: (*a*) only some – probably fewer than half – of the qualitative deficiencies in the production of health services are primarily educational; (*b*) only some of the basically educational problems can be solved by means of education, the rest being due to obstructions to the use of knowledge or skills; and (*c*) most quality-related educational programmes are concerned only with cognitive deficiencies, leaving affective aspects and psychomotor skills aside. Educational remedies may even be conducive to less than optimal quality. This is especially true if such measures are implemented wholesale, aiming at pushing the entire quality distribution towards a higher qualitative level – which often means more numerous, complex and costly services.

In many cases, the detection of qualitative deficiencies could be much more effectively exploited by means of organizational and administrative changes (*8,31,32*) or by providing immediate feedback on deviations from pre-established standards, without attempting to achieve any learning effects (*84,88*). Although quality assurance may aim at eliminating unnecessary operations and hospitalization, it all too seldom aims at eliminating unnecessary services, in spite of the increasing appearance of such words as "proper" in the operational definitions of quality. On the contrary, attention is most often focused on missing services, which easily leads to remedial actions that increase costs without really improving quality.

OBJECTIVES OF QUALITY-RELATED RESEARCH AND ACTIVITIES

The most important objectives of quality-related research and activities are as follows:

- pure research
- regulation
- policy planning and programme evaluation
- improvement of quality
- consumer protection
- screening for fraud

"Pure" research

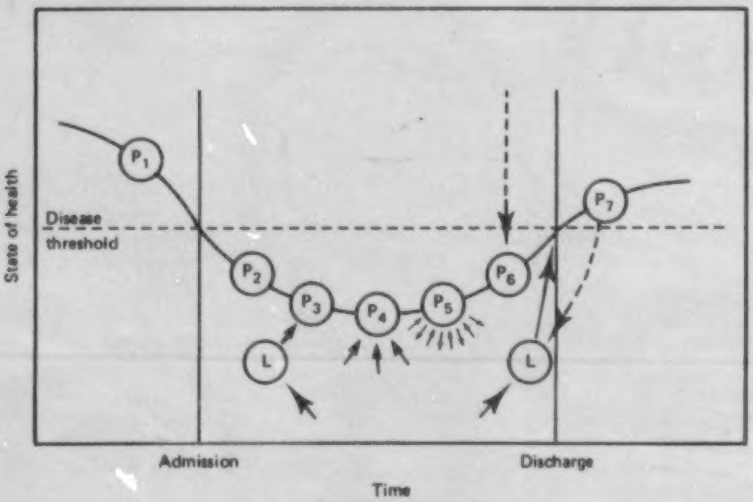
Pure research serves to clarify the concept of quality, to establish the relationship between the quality of health services and factors influencing it, to ascertain the methodological properties of instruments used in quality assurance programmes, and to act as a trouble-shooting mechanism.

Pure research often aims at the development of a model of quality and its determinants. Such a model can include variables pertaining, among others, to the following areas:

- *the consumer:* socioeconomic and demographic characteristics, attitudes, satisfaction, utilization patterns, etc.
- *the provider:* socioeconomic and demographic characteristics, type of specialty, participation in continuing education, professional affiliations, etc.
- *the organizational setting:* inpatient *v.* ambulatory care, solo *v.* group practice, remuneration system, size of the organization, etc.
- *the environment:* values of the society, the political system of the society, etc.
- *the health problem:* acute *v.* chronic, trivial *v.* serious, etc.

The model of factors influencing the quality of hospital care suggested by Sonkin (*89*) can be used as an example (Fig. 10).

Fig. 10. Factors influencing the quality of hospital care



P_1 : psychosocial background of the patient
P_2 : patient's illness and biological factors
P_3 : treatment habits of the physician
P_4 : standard of the hospital
P_5 : patient's attitude towards care and the hospital
P_6 : patient's contacts outside the hospital
P_7 : patient's home conditions
L : physician

This type of research presumes the collection of data on a great number of variables and a meticulous definition and implementation of these variables. The research design does not necessarily need to be very rigorous, since this research often has an exploratory and descriptive character. The situation changes if one wants to test the applicability of a model by systematically varying the independent variables and by observing the resulting changes in the quality of care. The state of the art has not quite reached this stage as yet.

Regulation

This is the oldest and a universal objective of quality assurance. It seeks to safeguard the consumer by guaranteeing acceptable minimum standards, although it has been claimed that the regulatory mechanisms may also serve the self-interest of the health professionals by limiting competition.

From the methodological point of view, measures having regulatory objectives are analogous to screening: a cut-off point has to be established, a suitable method has to be devised to find those below the cut-off point, and corrective measures have to be taken, such as granting or revoking the license to practise. Since poor performers are on the low quality tail of a more-or-less normal distribution of quality, there is usually no unequivocally definable cut-off point. This enhances the ethical imperative of developing a valid and sensitive measuring instrument so as to prevent social injustice to the health professionals. The other alternative is to place the cut-off point at such a low level that the the entire exercise becomes meaningless. According to several critics, this seems to be the case with many regulatory measures designed to guarantee minimum standards.

This ethico-methodological problem can be handled by using the measurement as a real screening device: those clearly above or below do not pose any problems, whereas those close to the cut-off point warrant a closer look.

Policy planning and programme evaluation

Routine quality assurance programmes virtually never provide conclusive evidence for comparing various systems of providing care. They may suggest that differences exist but, since they do not aim at controlling intervening variables, there is no way of telling whether one system should be preferred to another in planning for the future – a question often posed by decision-makers.

The question "Is A better than B?" has to be supplemented by a host of more specific questions such as "In which respect?", "From whose point of view?", "Within which time frame?" and "With what costs?". The decision-maker also wants to know whether the differences between two systems are due to factors that are amenable to manipulation by legislative, administrative, educational or some other means. To be able to tell that, the researcher has to design a controlled trial with appropriate experimental and control groups. The difficulties involved in conducting rigorously controlled experiments in the field of social policy are well known. They do not, however, justify jumping to premature and untenable conclusions on the basis of the results of routine quality assurance programmes designed for other purposes.

In this context, a distinction should be made between the performance of the system and performance within the system. The decision-maker is usually more interested in the performance of the system, whereas quality assurance programmes are concerned with the performance of the health professionals within the system. Efficiency and adequacy are primarily system characteristics, whereas effectiveness and especially the scientific–technical level of care pertain to the actions of the health professionals. Table 2 (p. 10) suggests that the interests of consumers, providers, and administrators and decision-makers may differ considerably with regard to these components.

Improving the quality of care

This naturally is the prime objective of the narrowly defined quality assurance programmes. To achieve this objective actual performance is measured and compared with the standards established for expected performance, the magnitude and causes of any deficits are determined, and appropriate remedial actions are implemented.

Consumer protection

Consumer protection could have been discussed under either of the previous two sections. It has, however, several peculiar methodological connotations that deserve separate treatment.

All the other objectives can be achieved by means of *ex post facto* arrangements; consumer protection – in the sense used here – presumes concurrent action. The focus is on individual patients and the care they are currently receiving. Ideally, the care should be monitored and modified continuously. Here the analogy to industrial quality control is perfect: the process is being monitored at critical points and the information obtained fed both *back* so as to modify the production before the next item reaches the point where something went wrong, and *forward* so as to correct to the extent possible the consequences of a previous faulty phase of the process. From society's point of view the "feedback loop" may be – at least economically – the more useful part of this cybernetic control, whereas the individual certainly appreciates more the "feed-forward loop" which protects him.

Clearly, this kind of continuous monitoring is not always feasible, but as an ideal model it warrants being kept in mind. In addition, there are certain sectors where the idea is already being implemented, such as the monitoring of patients in intensive care. An example that comes closer to our conventional view of quality assurance is a health information system that alerts the prescribing physician, ward or pharmacy to the possibility of overdoses or potentially dangerous drug interactions.

Screening for fraud

The routine methods of quality assurance have usually not been designed to detect exceedingly poor performance or performers, especially if the performance is downright fraudulous and the performer tries to conceal his actions.

The prime motivation of this kind of screening is safety: the weeds should be rooted out so as to protect the consumer. Screening may result in punitive action such as the permanent or temporary revocation of the licence of the health professional. Screening may also be justified on economic grounds, such as when the health insurance system or other financing mechanism is being abused by the submission of false claims.

The detection of poor and deviant performance may presume unannounced surprise checks and careful studies of all the material, especially records, pertaining to the care. The criteria used in the scrutiny may be kept secret so as to prevent conscious manipulation of the records. Patients may be consulted and re-examined so as to ascertain the degree to which the services claimed really have been performed. This type of screening is an exceptional application of quality assurance which presumes a strong and well-founded suspicion of wrongdoing.

There is a basic difference between screening to detect exceedingly poor performance and screening for regulation. In the first case, the providers of services have intentionally placed themselves outside the area where the conventional norms concerning health care apply, *i.e.* they have created a bimodal distribution of the quality of care. Consequently, the conceptual and ethical problems are less conspicuous since there is a clear cut-off point. The detection of such performance may, however, be complicated by attempts to conceal poor performance.

THE FOCUS OF QUALITY ASSURANCE

The division of the production of health services into three components (structure, process and outcome) originally suggested by Donbedian (*4,5*) has generally been accepted as a point of departure for classifying quality assurance programmes. Constanzo & Vertinsky (*90*) have illustrated these approaches, as shown in Fig. 11.

The value and relevance of these approaches for quality assurance has, at times, been the subject of a somewhat heated debate. Part of the disagreement has resulted from the fact that the objectives of the various approaches have not always been clearly spelled out. Currently, there seems to be fairly good agreement that the emphasis should be on outcome and that the structural approach offers the least promising avenue to high quality.

Another source of diverging opinion has been the most appropriate way to define the care to be scrutinized. In most cases the starting point is a single procedure, such as a diagnostic test or an operation. These procedures can, however, be looked at from many angles and they can be grouped in different ways. They can, for instance, be grouped to reflect the care given by a provider disregarding the recipient of the care, the care received by a patient disregarding who has contributed to it, the care given in an institution, or even the "quality" of the health care system as a whole. In most cases, quality assurance focuses on the care given by a provider.

In this context, Weed (*91*) has drawn attention to a profound problem. He has forcefully and rather convincingly argued that the performance of the system and the performance of a provider within the system have to be separated. According to him, a meaningful quality assurance system presumes the existence of:

(*a*) a health care system that defines the rules;

(*b*) a monitoring system to measure the performance of the health professionals within the system; and

(*c*) a monitoring system to measure the outcome of the system.

The crucial point is that health professionals cannot be held accountable for the outcome of care, since the rules of the game have been laid down and the preconditions have been provided by the system. For the health professional, the question is not what he has accomplished but how he has applied the rules.

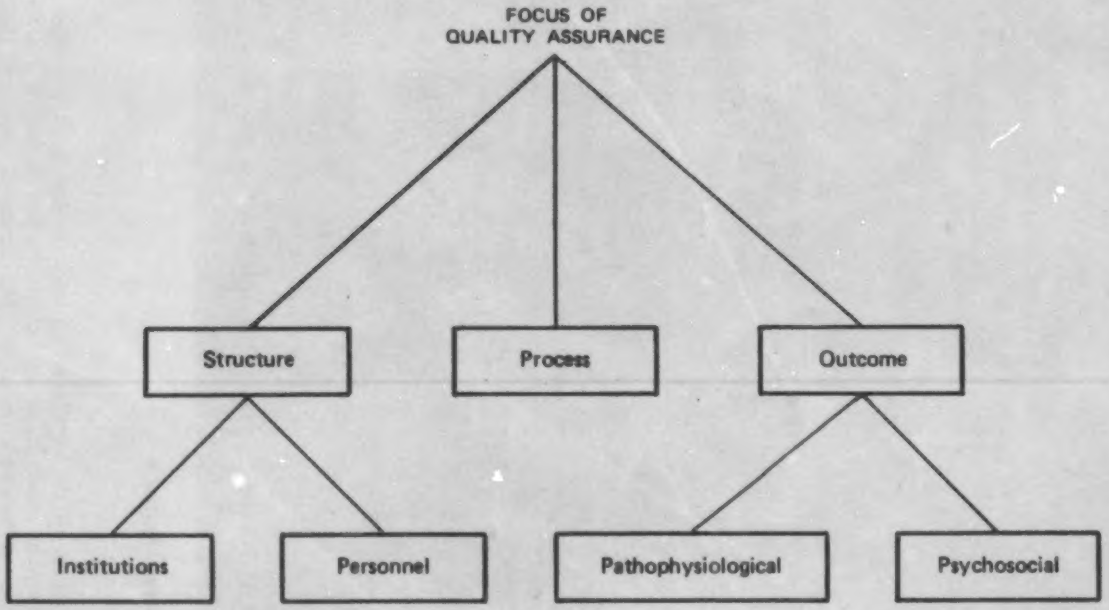


Fig. 11. The classification of quality assurance methods

FOCUS OF
QUALITY ASSURANCE
Structure
Process
Outcome
Institutions
Personnel
Pathophysiological
Psychosocial

If one accepts Weed's point of view, the appropriate area of application of the three basic approaches to quality assurance has to be redefined: a provider's performance can only be measured in terms of his behaviour (i.e. process), whereas both the structural and the outcome approaches are applicable to system performance, the outcome approach providing more valid information. In addition, the attributes of a provider's performance to be monitored also have to be redefined. Weed suggests the following four attributes: thoroughness, reliability, efficiency and analytical sense. Should the provider exhibit these attributes, only the system or the natural history of the disease can be blamed for any possible poor outcome.

Rutstein et al. (*92*) make the same distinction between the process within the system and the outcome of the system, but their conclusions differ somewhat from those of Weed. According to them, quality in the proper sense of the word is the output of the medical-care machine in the form of better health, whereas the internal functioning of the machine can be measured in terms of efficiency. Most current measurements of medical care are concerned with efficiency, but making medical care more efficient does not necessarily improve its quality. Improvement in quality has to be verified by direct measurement of the improved health of the individual and of the population served. These authors suggest that the difficulty of measuring increasing levels of positive health can be overcome by establishing quantitative negative indices of health. Cases of unnecessary disease, unnecessary disability and untimely death can be counted. Their occurrence is a warning signal that the quality of care may need to be improved. The difference between Weed's thinking and theirs is that they feel that a provider can be at least partly responsible for failure of the system, although they explicitly point out that investigating the causes of the event may show that identifiable social, environmental, "lifestyle", economic or genetic factors are responsible for its occurrence.

Rosenthal (*25*) has emphasized the difference between quality per unit of procedure and quality over the system as a whole. A procedure which, when assessed separately, may be of high quality, can actually represent poor quality from a system point of view if produced in the wrong place or for the wrong patient. This problem can best be handled by means of the concept of optimum quality.

The structural approach

Rationale

The rationale of the structural approach is that good preconditions are more likely to result in an appropriate process of care and a favourable outcome than poor preconditions. The structural approach thus constitutes an *ex ante* method. In the structural approach the input into the health care process, i.e. resources in terms of health manpower, facilities and equipment, is described and compared against established criteria and standards.

Origins

The origin of the structural approach in health care can be traced back to the famous Flexner report (*93*). Flexner – and his employer, the Carnegie Foundation for the Advancement of Teaching – was concerned with the quality of medical education. He made site visits to all American and Canadian medical schools. He used criteria such as the staff, the financial resources of the schools and – perhaps most important – the laboratory and clinical facilities, and compared them with those of the Johns Hopkin's School of Medicine which, for him, constituted the model of a structure conducive to high quality education. He considered medical education to be one of the most powerful strategies for improving medical care. He also strongly advocated compulsory licensure for physicians, specialization and continuing education. In fact, he envisaged most of the strategies that have later been suggested in connexion with the structural approach: basic education, specialization, continuing education and licensure. The most important missing component of structural approach in Flexner's arsenal was that of instituting a formal mechanism for the accreditation of health care institutions other than medical schools.

Types of structural approach

The most important quality assurance programmes based on the structural approach are education and credentialing of institutions and personnel. Basic education is often a criterion used in credentialing. Continuing education is a structural approach strategy only when there are requirements for mandatory continuing education (e.g. every physician should have at least five weeks of continuing education during every two-year period) which are not aimed at correcting specific deficiencies in care detected by means of quality assessment. "Tailor-made" continuing education designed to correct such deficiencies is a strategy primarily related to the process approach.

Credentialing comprises three activities (*94*).

1. Accreditation. The process by which an agency or organization evaluates and recognizes an institution or programme of study that meets certain predetermined standards.

2. Licensure. The process by which a government agency grants permission to persons to engage in a given profession or occupation by certifying that those licensed have attained a predetermined degree of competence.

3. Certification and/or registration. The process by which a non-governmental agency or association grants recognition to an individual who has met certain predetermined qualifications. Such qualifications may include (*a*) graduation from an accredited or approved programme; (*b*) acceptable performance in a qualifying examination; (*c*) completion of a given amount of work experience; and (*d*) association membership.

Accreditation. This process concerns educational and health care institutions and programmes and aims at protecting both the public and the prospective professionals by guaranteeing that an institution has the capability of producing competent professionals and high quality services. Both licensure and certification concern health professionals and aim at protecting the public. The privately sponsored accreditation and certification programmes may be more effective in quality assurance than the public licensure programmes, because they often apply higher standards. In fact, many critics claim that legal regulatory measures may be meaningless because of the loose standards.

Accreditation usually refers to voluntary activities initiated by the professions or institutions whose functioning is under scrutiny, whereas the term "licensing" usually refers to government activities based on law. An accreditation programme may develop into a licensing programme. In many countries, personnel are licensed but institutions are accredited.

The best known accreditation programme was developed by the American College of Surgeons a few years after the publication of the Flexner report. The College first tried to employ the end-result (outcome) method suggested by Codman (*95*) but the results were so discouraging that it was quickly decided that the basic standard had first to be raised by improving the structure of the health care institutions. This endeavour later resulted in the foundation of the Joint Commission on Accreditation of Hospitals (JCAH). The Commission developed detailed structural criteria for hospitals covering, for example, equipment and staffing, staff training, the use of quality assurance methods, organizational arrangements and financing mechanisms.

In the structural approach, the elements under scrutiny are compared against pre-established criteria. On each criterion there is a value – the standard – that is deemed to indicate acceptable quality. Usually, minimum standards are applied, which means that the institution has to meet the standards in full to be accredited. There may be different standards, however, depending on the objectives and hierarchical position of the institution. This phasing of standards is relatively easy in countries with a clearly defined hierarchy of health care institutions, whereas countries with primarily private and uncoordinated institutions may have to make do with just one set of standards. This may easily result in their being too low to have any practical significance.

The criteria are often of an all-or-nothing nature, i.e. they only have two values, 0 and 1, the latter being the standard. The results of applying such criteria are usually presented criterion-by-criterion, indicating whether the criterion has been met or not. Such results provide clear guidelines for action: all 0s have to be rectified. Scaled criteria (i.e. those that can take on a set of values) offer more alternatives for the presentation of results. Scaled criteria also enable the development of a composite index to indicate the "structural goodness" of an institution by means of a single figure. This procedure presumes that the criteria can be weighted appropriately. This is not always the case, although O'Malley & Kossack (*96*) found that various hospital experts concordantly ranked the criteria suggested by JCAH as to their relative importance. If the methodological difficulties connected with the composite index were capable of being solved, the index could be useful in comparative studies. Its practical usefulness would still be very limited, however, since the same score could be achieved in many ways and the index would not indicate where the weaknesses and strengths of an institution lay. It would provide a poor basis for planning remedial action.

Scaled criteria would also permit the presentation of results in the form of a profile indicating the score the institution has received on each criterion or on a combination of them. Such a profile could be compared conveniently with the averages or other statistics describing, for example, similar institutions or other institutions in the same region (*97*).

In summary, accreditation concerns the approval of health care institutions for their intended use. Such institutions can be approved before they begin operation and reapproved on the basis of periodical re-examination. The criteria and standards used in the accreditation may have three objectives.

1. To prevent public hazards. Standards serving this objective are related to various structural properties of the facility such as electricity, plumbing and construction materials. The standards safeguard both the personnel and the clients against nonmedical hazards. The standards are contained in various codes, and inspection is usually carried out by nonmedical personnel. All European countries have some degree of this kind of control.

2. To guarantee minimum medical standards. Standards concerning this objective include the type, amount, and quality of equipment and the number, training, and other qualifications of personnel. There is a clear correlation between the degree of such control and the role of society in running and financing the health care institutions.

3. To increase the efficiency of health services. Standards serving this objective stipulate the kind of activities that should and should not be carried out in various health care institutions. They often aim at a hierarchical, regionalized health care system. Again, there is a clear correlation between the role of the state in the health care system and the degree to which the activities of the health care institutions are regulated.

In Europe, the fulfilment of standards is usually checked only at the time of the original approval or after major changes or extensions. Periodic re-examination is rare and usually not related to re-accreditation. In socialist countries, original plans have to comply with very detailed standards and compliance is checked by national health authorities before approval. Capitalist countries usually give more responsibility to local authorities or other owners of the institutions.

Many countries have found it necessary to establish either permanent committees or *ad hoc* task forces to advise the health authorities on the acquisition of expensive and technologically sophisticated equipment. The work of such committees often results in the issuance of new structural qualitative standards.

Licensure. According to students of the sociology of professions, all aspiring professions aim at acquiring the control of training institutions and programmes and of the entry into the profession. The establishment of a licensure system is the ultimate symbol that a profession has reached maturity and been recognized as sufficiently important to warrant such societal regulation.

The licensure system has typically progressed from permissive or friendly (preventing the use of a given title by the unlicensed) to mandatory or unfriendly (making criminal any action within a licensed profession by one not licensed in that profession) (*98*). Another typical feature is that licensure has spread from those occupational groups (such as physicians and dentists) that can engage in an independent economic activity such as private practice, to those that produce supporting services (e.g. physiotherapists in countries where a prescription by a physician is required for physiotherapy).

In many countries the implementation of the licensure system has been entrusted to the profession because, until recently, the legal conditions for gaining permission to engage in an activity and their control were deemed a purely professional matter with few and unimportant social consequences. In this respect, attitudes are quickly changing. Licensure, perhaps the most time-honoured and unchallenged strategy to guarantee a minimum standard, has come under increasing attack. It is recognized that mandatory licensure in particular may create problems. Critics have either claimed that licensure serves other purposes than is generally assumed and professed, or questioned its efficiency in achieving its alleged objectives.

In the first group some *laissez-faire* economists, such as Friedman (*99*), bluntly maintain that licensure – as all restrictions of free competition – is inherently bad and inevitably results in decreased quality and quantity of production. Some sociologists, such as Freidson (*26*), seem to agree with George Bernard Shaw that "every profession is a conspiracy against the laity" (*The doctor's dilemma*). For them, licensure constitutes just another method of maintaining power and controlling entry into the profession. The second group of critics claims that, because of many problems of principle and method, the licensure system is not particularly effective in protecting the consumers. Their imputations can be condensed into three interrelated questions: (*a*) does licensure really guarantee minimum standards? (*b*) how does it influence the division of labour? and (*c*) how does it influence professional training?

Many licensure laws date from a time when the knowledge explosion was an unknown problem. They do not recognize that the advancement of medicine renders a person's initial qualifications obsolete unless they are periodically upgraded. Although licensure may be based on an examination at the end of training, it is no guarantee that the knowledge mastered at the time of the examination will be retained or that the knowledge ever was or will remain relevant. The conclusion is that licensure cannot guarantee even minimum standards because of the problem of educational obsolescence. In many countries, the system is "once a physician, always a physician". It seldom contains any provisions for the renewal of the initial qualifications. In the worst case, licensure may be conducive to poor quality because rigid laws may prevent needed educational reforms and give an unscientific, obsolete system a cloak of legal respectability and social approval.

Perhaps the most important problem with licensure is its impact on the division of labour and delegation of tasks. The development of medicine has necessitated new tasks that could safely be delegated from highly trained groups to some new or existing groups with less training. Delegation may, however, be illegal, because the laws often stem from a period when there was no need for such a delegation. The underlying legal principle is based on the general negligence theory. If a task that, according to the law, belongs to the responsibility of a certain personnel category is, in turn, delegated to another category that is not explicitly authorized to perform that duty, then an act of negligence may have been committed. The mounting fear of malpractice litigation has aggravated the problem: health professionals are very reluctant to delegate tasks without a clear legal basis even when it would be clearly desirable. An additional complication is that some professions take recourse to licensure laws to actively oppose a new – and perhaps more purposeful – division of labour if they fear that it lowers their status or endangers their professional autonomy. This leads to an unnecessary fragmentation of health care and provides a bad example for new, aspiring groups of personnel who may also wish to achieve a legally guaranteed autonomy when cooperation, teamwork, and interchangeability of tasks would be more appropriate.

The solution of problems related to educational obsolescence and delegation of tasks calls for educational innovations: reformed curricula for existing personnel and innovative training programmes for new personnel. Rigid accreditation and licensure programmes that pay undue attention to educational processes and formal prerequisites instead of to the achievement of objectives may render such reforms impossible. To avoid this, the law should provide an opportunity to implement new educational programmes on the basis of administrative rather than legal decisions and changes.

The paralysing effect of licensure laws may be particularly marked if the licensure process has been completely entrusted to the profession in question. If a new division of labour is experienced as a threat, there may be intentional attempts – very often waving the banner of "high quality care" – to prevent the emergence of new professions. More often, however, the untoward effects of the biased composition of the licensing bodies are caused by ignorance of the capabilities of the new personnel groups. As the educational atmosphere of the established professions is not particularly conducive to teamwork, and the system does not expose professionals to the capabilities of new groups, professional isolation tends to perpetuate. The licensing bodies also have a tendency to define licensing requirements from a purely professional point of view without taking into account the expectations of consumers, especially when there are no representatives of health authorities or consumers in the licensing bodies.

To summarize the discussion on the licensure system, licensure laws are needed to accomplish their original purpose – the protection of the public against quacks. To avoid various drawbacks, laws should be subjected to periodic scrutiny and be written in a way that permits necessary adjustments and modifications as a result of educational, medical, technological and practical developments. Furthermore, the membership of the licensing bodies should be broadened to include representatives of the public and other categories of health personnel. In spite of such improvements, the licensing system cannot be an adequate quality assurance mechanism. It relies too heavily on penal or quasi-penal sanctions and it will remain too rigid to respond swiftly to the changes in medicine and professional education. Periodic relicensure, based on explicit continuing education and practice requirements and aiming at correcting observed deficiencies, would be a step in the right direction, but does not yet eliminate the need for process and outcome approaches. Pointing out that the automobile industry would never consider proof of attendance by its mechanics in continuing education courses a satisfactory and adequate quality control method, Templeton (*100*) suggests that the relicensure be linked to how a professional fares with systematic quality assurance programmes. Such programmes should cover the professional's level of knowledge, management of unusual situations, management of everyday practice, and affective, psychomotor and perceptive factors related to care.

Relicensure. "The recognition of a doctor's competence to practise medicine after he has completed such (basic) education satisfactorily should be a once-for-all matter, lost only through deterioration of mind or body by age or illness" (*101*) is an opinion that can still be heard. However, an increasing number of health authorities, educators and practitioners hold that licensure is an inadequate guarantee against professional obsolescence and that "periodic relicensure is a reasonable approach for ensuring continuing competence in medical practice" (*30*). While there is consensus on the importance of relicensure, opinions on the use of continuing education as a requirement for relicensure are divided.

There are objections of both principle and practice. There are those who believe that continuing education should always be voluntary and left to the conscience of professionals and that mandatory continuing education defies its own purpose by becoming an unpleasant task. The pragmatic objections concern the effectiveness, costs, quality, resources and manpower consequences of mandatory continuing education. Mandatory continuing education will greatly increase the number of recipients and thus logistic problems and costs. Given the difficulties connected with the provision of relevant voluntary continuing education, how can we guarantee that the much greater volume of mandatory education will be relevant and of high quality? For the training to serve any purpose at all, the achievement of its objectives has to be evaluated. Templeton (*100*) suggests that such testing should consist of a periodic assessment of the physician's cognitive, affective, perceptive and psychomotor skills, as well as of his ability to manage a variety of less common but important conditions. Relicensure could be linked to how the physician fares with systematic quality assurance programmes, such as medical audit. Clearly, the methodology is very embryonic and the resources totally inadequate for such an ambitious undertaking. There are unsolved problems, such as who should assume the tremendous costs – the trainee, his possible employer, or society – and what should be done with those who fail to achieve the objectives of this training. In short, it has been feared that a good intention may lead to the provision of substandard education that does not serve any worthwhile purpose.

In spite of these – admittedly very real – problems, the proponents of mandatory continuing education claim that even a deficient system is better than no system, and constitutes the only way to force those who probably would never avail themselves of voluntary continuing education to participate in some kind of training that upgrades their skills and knowledge. It seems to me that mandatory continuing education as a prerequisite for relicensure is the right policy. The above problems have to be faced squarely. By adhering to the principles of adult education and by implementing the system gradually, many problems can be overcome. It should, however, be stressed that without careful planning and skilful implementation, the system may badly backfire.

In Europe, licensure laws can be found in all countries. With regard to the physician such laws are almost exclusively mandatory, i.e. it is a criminal act for anyone to act as a physician without being licensed. With regard to the other categories of health personnel, the law can be permissive as well, i.e. simply the title of a health profession is protected against use by unlicensed persons.

No country requires periodic relicensing, although the desirability of such a procedure has been discussed in many countries. The medical profession is opposed to a mandatory relicensing system, even though it strongly favours initial licensing. There are also signs of mounting opposition to licensure. It has been claimed that licensure requirements should be dropped. Although this position has not gained widespread support, even many of its opponents in the higher echelons of national health authorities are acutely aware of the blocking effect of licensing requirements on the most purposeful deployment of existing and, above all, new categories of health manpower. The prime objective of licensing requirements – the guarantee of a minimum standard for health professionals – is, however, considered more important than any adverse effects licensing may have.

Basic education and quality control. Since the Flexner report, basic education has been considered the major vehicle for guaranteeing high quality, and its value has hardly ever been challenged. After all, knowledge and skills learned during basic education are the most important tools of the health professional. The relevance of the current mode of education to high quality services has, however, come under increasing attack. Therefore, some educational issues of specific relevance for the structural approach, such as educational objectives, task analysis, professional ethics and behavioural aspects, will be touched on briefly.

According to Kane et al. (*102*) one of the basic problems is that the end-product of medical education has not been defined. This renders the specification of educational objectives, the development of content, and the selection of the most appropriate teaching methods and settings difficult. A good indication of the poorly defined end-product is the controversy as to whether a medical graduate should be a "basic physician" capable of independent, unsupervised work, or an "educated man who becomes fully qualified after postgraduate training" (*103*). Some countries such as the Soviet Union have chosen the first alternative, offering medical students the possibility of beginning their specialization on the first day of their studies. Others emphasize the concept of life-long learning and require a special supervised training period after graduation before a physician can practise independently.

Jason (*104*) claims that medical education has emerged from gradual, largely unplanned, evolution rather than having been guided by either informed leadership or systematic research. This has resulted in a widening gap between training and work. Medical education is given in places where only a tiny fraction of patients, those with the rarest problems, are being treated. Attitudes and communication skills are largely neglected. Virtually no attention is given to outpatient settings or to the psychosocial problems of patients. The student physicians have too few role models and – as Jason puts it – "we immerse students in the skills of being followers in preparation for careers as leaders". They do not learn a self-critical attitude, characteristic of leaders and of paramount importance for effective quality assurance. One particularly neglected aspect is training for cooperation with other categories of health personnel, although teamwork is professed to be the mode of action of the day (*105*).

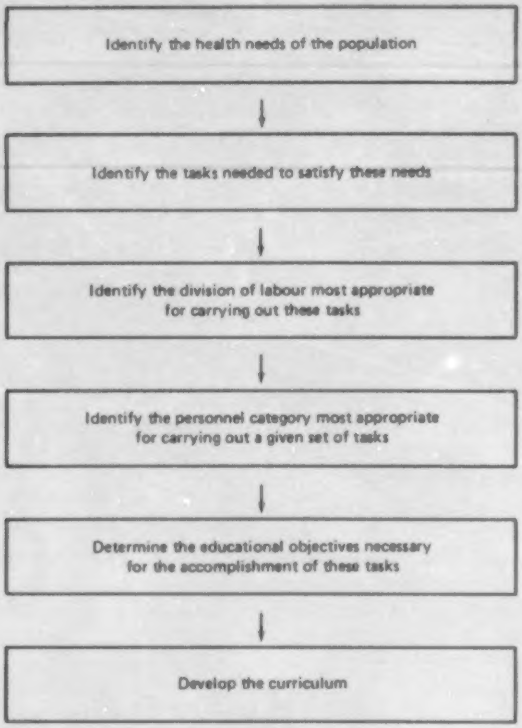
It is unfair to expect that students trained in a way irrelevant to their future tasks would master these tasks. The solution lies in educational objectives and content based on a task analysis. A WHO working group (*106*) recommended that a particular process be followed in curriculum development, as shown in Fig. 12.

In this process, two points deserve special emphasis: the division of labour in health care should be based on task analysis, and the educational objectives of the training of each personnel category should be stated explicitly. If this were the case now, most of the problems alluded to in connexion with the licensure system would have been solved long ago. With regard to educational objectives, a balance has to be struck between the competing goals of safety and professional satisfaction. On the one hand, the safety of the consumer presumes that health professionals be thoroughly trained and that they master the necessary skills and knowledge. On the other hand, to be attractive for a practitioner, his work has to be a continuous challenge; he has to be allowed and stimulated to work close to the upper limit of his qualifications.

What are the proper entrance requirements for medical students? This is a special quality-related educational problem. As Fenninger (*107*) has noted, much of the formation of a person takes place early on in life and in the first years of education. Courage, compassion, integrity, generosity, and intellectual curiosity are not acquired in formal courses in professional schools. The experience of many countries has been that the behaviour and attitudes of many physicians leave much to be desired. Several studies have amply demonstrated that, at least from the consumer's point of view, the behaviour of a health professional is an important qualitative aspect of the care. Unfortunately, other studies have shown as convincingly that changing basic character traits or imparting desirable attitudes is quite difficult. Psychological testing in connexion with entrance examinations has produced meagre results. In addition, the justification of such testing can be challenged: health care is a tremendously vast field that can accommodate all kinds of personality should a proper niche be found for them. The solution may lie in intensified vocational counselling and in sensitivity training designed to make students at least aware of the importance of interpersonal factors in health care.

The ethos of a profession, embodied in the code of ethics, can exert a great influence on the educational atmosphere and on the conduct of individual

Fig. 12. The curriculum development process


Identify the health needs of the population
Identify the tasks needed to satisfy these needs
Identify the division of labour most appropriate for carrying out these tasks
Identify the personnel category most appropriate for carrying out a given set of tasks
Determine the educational objectives necessary for the accomplishment of these tasks
Develop the curriculum

professionals. Therefore, in teaching professional ethics, quality considerations – particularly as seen from the patient's point of view – should be emphasized to promote the "intangible" aspects of good care. The fact that the content of the code of ethics is almost exclusively determined by the professionals themselves underscores their responsibility. This responsibility is further enhanced by the fact that the profession often controls entry into medicine and the content of medical education.

In Europe, trust in the value of basic education in guaranteeing a minimum standard, and in raising this standard if need be, seems to be unchallenged. In many countries, continuing education is mandatory or consideration is being given to making it mandatory. It is, however, seldom based on an analysis of the educational needs of health professionals. The content is more often than not derived from the research interests of the teachers running the courses at the academic institution. Being exposed to the latest advances in science will not necessarily enable practitioners to provide better care in their day-to-day work.

In the case of routine quality assurance programmes, education is almost invariably the remedial method of choice. In the German Democratic Republic and Hungary, physicians whose performance has been found to deviate from the established norms can be sent to refresher courses. In the Soviet Union, physicians are graded according to their qualifications and each is assigned to one of three categories: supreme, first level, and second level. The assignment depends on years of experience, research conducted, papers published, and refresher courses taken.

The mandatory specialization of all physicians can be considered a special case of using education as a structural means to improve the quality of care. In some socialist countries, all physicians are specialists. In addition, there is usually special administrative and managerial training for physicians in leading positions, and they often have to be both clinical specialists and specialists in social medicine. Such training often contains elements related to the quality of services, since there is assumed to be a high correlation between the level of administrative competence and the quality of care provided in health care institutions.

Many European countries are concerned with the alleged deterioration of the doctor–patient relationship. The usual antidote has been increased training in social sciences, but the results have been rather meagre.

Evaluation of the structural approach

In evaluation, validity assumptions play an important role (*10*). They are hypotheses concerning the logical sequence of events, their interrelationships, and their contribution to the achievement of the objectives of the programme. Screening for the early detection of diabetes illustrates this. The ultimate goal of the programme is to prolong life and improve its quality; diabetes is considered to contribute negatively to these goals. The sequence of events and the chain of validity assumptions might run as follows: the test used in screening is a reliable method of detecting diabetes at an early stage; the programme can be extended to cover the population at risk; early detection leads to the initiation of treatment; people will adhere to the regimen prescribed; the treatment will change the natural history of diabetes; this change will result in fewer and milder symptoms and complications; a better balance in the sugar metabolism will increase the life expectancy of people with diabetes.

Some of those assumptions have been proved correct, many are just assumptions. Obviously, the longer the chain of validity assumptions becomes, the more likely it is to contain weak, logically untenable and unproved links that may ruin the entire programme. In the structural approach to quality assurance, the main links consist of the assumptions that good structure guarantees the appropriate process and this, in turn, ensures a good outcome.

In this chain, the structure is far removed from the objective (i.e. outcome). Thus, from the theoretical point of view, the structural approach must be the weakest quality assurance approach. The results of studies that have been designed to ascertain the validity of the structural approach seem to corroborate the theoretical expectations. Some correlation has been found between such factors as the type of practice and equipment available and the length of internship on the one hand, and the outcome of care on the other. For instance, Graham (*108*) concludes in his literature review that the available – admittedly limited – evidence supports group practice as having advantages over solo practice in terms of accessibility, quality, continuity and efficiency, whereas Roos (*109*) claims on the basis of her study in Manitoba that the productivity and quality gains often associated with group practice may have been overrated. Rhee et al. (*110*) found in their study in Hawaii that, when general practitioners practised without limitation, their quality of care was not as good as that of specialists. Similarly, when specialists practised outside their specialty areas, the relative quality of their performance declined. In spite of these findings – in my mind rather obvious ones if there is any sense in having specialization – the authors caution against rigid restrictive structural checks to guarantee higher quality.

The overwhelming consensus is that the validity of the structural approach is poor (*7,111,112*). Greene (*7*) states that assessment from structure alone can be misleading unless a specific structural item is used which has a proven relationship (positive or negative) with outcome. Worse still, reliance on structural measures can adversely affect quality, as where regulations inhibit innovation, or when professional qualifications for a particular task are raised so high that there are not enough personnel to service all in need. Jonas (*112*) is even more unequivocal in his condemnation of the structural approach: "It has indeed never been shown that there is any relationship between retrospective measurements of the quality of medical care undertaken using structural methods and those undertaken using process and/or outcome techniques". Brook (*20*), however, makes a minor concession by granting that structural data, if collected by an unannounced *ad hoc* sampling technique, may provide a relatively inexpensive and successful control over fraud.

To summarize, the licensure system still has a role to play in protection against quacks, some structural data can be used to detect overt fraud and, although a good structure does not guarantee a favourable outcome (for example, resources can always be under-, over- or misutilized, and management can be poor), it may prevent a deterioration of quality that could result if there were no minimum standards or other structural safeguards.

The process approach

Rationale

This approach is based on the assumption that if, in all phases of care, currently available medical knowledge and technology are fully applied, the outcome is more likely to be good than if the application of medical knowledge and technology is deficient.

Origins and development

The earliest attempts to introduce quality assurance were based on outcome. Since these failed, the pioneers of quality assurance looked for something else.

The structural approach was the immediate answer but, when this also proved unsatisfactory, the next logical step was to turn to the process of care.

In the literature, no direct reference to the experience gained in industrial quality control can be found, but the notion of health care as a production process rapidly gained a foothold among students of health care in the early 1950s. Another control mechanism already applied in health care, fiscal auditing, certainly influenced their way of thinking. It was suggested that, just as the ledgers of a health care institution are subject to fiscal auditing, so the production of health services should be subject to medical auditing (*113,114*).

This analogy also suggested the most appropriate source of information for medical auditing: the medical records of patients where the process of care is recorded. The recorded process of care was considered the most tangible thing upon which to base an evaluation of health care. The rationale of this approach – that an appropriate process guarantees good results – was accepted almost unquestioningly. Lembcke (*48,115–117*), the main protagonist of this approach, was instrumental in developing the method now commonly known as medical audit. He strongly emphasized the use of objective criteria and scientific methods. He was able to demonstrate the educational value of quality assurance and its capacity to improve care.

Types of process approach

Donabedian (*21*) has suggested the classification of quality assurance methods shown in Fig. 13. This classification applies to all approaches, but it is probably most illustrative in the case of the process approach. The type of criteria (implicit *v.* explicit) and the type of standards (empirical *v.* normative) have sometimes been added to this classification scheme.

An *internal evaluation* is carried out by the personnel of the institution under scrutiny. In the case of an *external evaluation*, the assessor may represent any body outside the institution, such as a professional association, educational institution, statutory body, research group or commercial enterprise. The affiliation of the assessor depends on the objectives of the evaluation. Evaluation for policy-making, fraud screening, accreditation or licensure purposes should be external, whereas quality assurance in the narrow sense of the term should be entrusted to those whose activities are to be scrutinized. An external evaluation is, of course, less subject to accusations of whitewashing and cover-up, whereas an internal evaluation is more acceptable to the health professions. It may also be more flexible and more relevant to the identification of problems amenable to solution by organizational and educational means.

An *administrative evaluation* usually focuses on the use of resources in the production of health services, and serves planning, management and accounting purposes. The focus of a *professional evaluation* is primarily the scientific-technical quality of the services produced. For administrative purposes, an external evaluation is often desirable, whereas an internal evaluation is usually more appropriate for professional purposes.

In *case review*, the care given by a provider or received by a patient, revealed by the medical records, is the object of assessment. Participatory observation has also been used but, because of the great costs involved, this method hardly

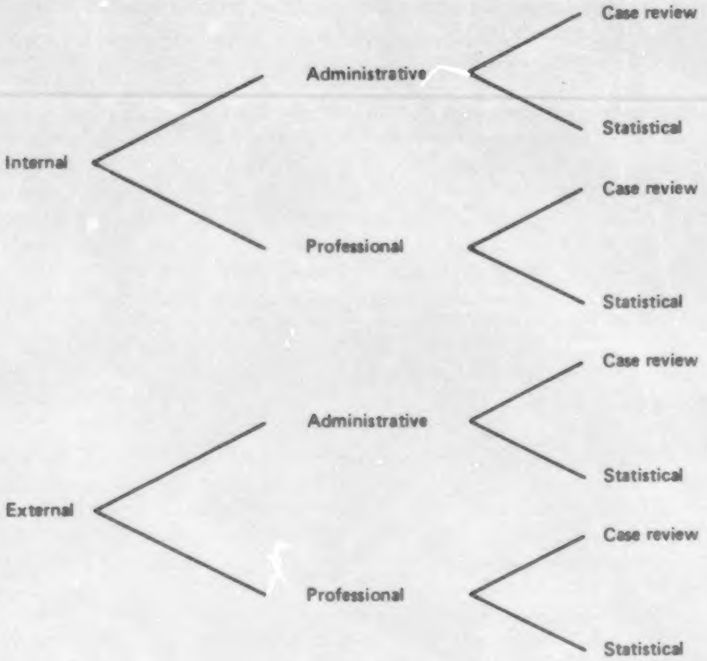

Internal
Administrative
Case review
Statistical
Professional
Case review
Statistical
External
Administrative
Case review
Statistical
Professional
Case review
Statistical

Fig. 13. The classification of quality assurance methods based on the process approach

lends itself to routine use. The data obtained can be aggregated so as to depict patterns of care. The crucial feature, however, is that the analysis starts from a record or from the observation of a given situation. The *statistical method* begins with statistical aggregates compiled from individual records. As a consequence, the assessor does not need to study the source documents at all, although in most cases the statistics are used to single out those that require a more detailed analysis. To put it concisely, the case review proceeds from source documents or individual observations to the identification of patterns and the making of generalizations; the statistical method begins with aggregate data and may then proceed to a detailed analysis of those source documents that have given rise to conspicuous findings.

The types of criteria and standards are discussed in chapter 4. There follows descriptions of the two most commonly used routine process methods, the utilization review and the medical audit.

Utilization review. In the United States, hospitals that wish to be reimbursed for the treatment of patients entitled to certain social security benefits are obliged to establish a utilization review system (a peer services review organization, PSRO).[a] According to the law, the purpose of a PSRO is to promote the effective, efficient and economical delivery of health care services of proper quality. To this effect, the PSROs have to determine whether (*a*) services and items are medically necessary, and (*b*) it is necessary to provide them on an inpatient basis.

Of the stated purposes, clearly those related to economy as opposed to quality have dominated the activities of most PSROs; for example, over-use of services, too long a stay, and unnecessary hospitalization are much greater concerns than under-use, too short a stay, and a needed hospitalization that never materialized. This readily gives rise to an argument that this kind of control – under the guise of quality assurance – is actually conducive to poor quality care and may, therefore, render all quality assurance activities dubious and unacceptable to the health professionals. The idea of requesting health professionals to justify the use of expensive resources and of monitoring their use is, however, completely in accordance with the increasing emphasis on the optimal and logical quality of care. Given the rising costs of health care, the practice should not be discarded because of disillusionment with, or openly hostile reaction to, the PSRO system.

Medical audit. According to the conventional use of the term, medical audit can be defined as a retrospective assessment of the quality of care on the basis of medical records. Medical audit usually, but not necessarily, focuses on the process of care. It presumes the development of a model of good care consisting of criteria pertaining to the medical history, diagnosis, treatment, follow-up, and rehabilitation. This model contains items that should – or should not – have been performed as part of the treatment process. The assessment consists of comparing the actual care against this model. Slee (*82*) illustrates this idea as follows:

Care given
v.
criteria
= Medical audit

Medical audit is a routine quality assurance method in a large number of North American hospitals, but is rarely found elsewhere.

In large hospitals, there may be an audit committee for each medical specialty; in smaller ones, there may be one for the entire institution. Several small hospitals may also pool their resources to have a common audit committee. The committee chooses the diseases (or conditions or operations) to be audited; either accepts criteria developed by others, modifies such criteria or develops its own; sets standards for acceptable care; and decides what information is needed from the patient records to determine whether the criteria have or have not been met. In the case of a limited specialty, small hospitals or known specific problems, all cases can be examined. More often a sample is considered to be sufficient. Sometimes the audit committee wants to see all records; usually, however, a clerk checks the records and selects those in which there are discrepancies between the actual care and the criteria. The committee then examines these records in detail.

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[a] Details of the PSRO system may be found in the PSRO program manual (*118*) or in Goran et al. (*119*).

The committee tries to identify problem patterns. Should such emerge, the committee attempts to ascertain their causes. The last step consists of deciding on needed remedial action and its implementation. In early efforts, simple feedback was considered to be enough: the providers of the services were informed about the results of the audit and it was assumed that they would draw the appropriate conclusions.

In rare cases, a continuous monitoring of all care or certain types of care given by a provider is deemed necessary. Even fewer cases may lead to sanctions such as a permanent or temporary revocation of the privilege to perform certain operations. Punitive sanctions are considered to be undesirable and the impact of simple feedback of the results insufficient. Thus, there is increasing emphasis on gearing the audit findings to a systematic continuing education programme.

Continuing education as a strategy in the process approach[a]

Continuing education has two main tasks: to keep health professionals up to date and to correct observed deficiencies in the quality of care. Greene (*7*) describes six approaches to improving physician performance by means of continuing education.

1. Content model. This is the traditional approach based on the assumption that a physician will choose the continuing education programmes most appropriate for his needs and translate the acquired knowledge into practice. Several studies have demonstrated the impact of such training to be rather poor. Greene (*7*) summarizes the results of such studies as follows: "participation in continuing education programs cannot be assumed to improve physician performance. Whereas it could be argued that wholesale continuing education for physicians could hardly do harm to the quality of physician performance, it is likely that more cost effective alternatives exist for improving the quality of medical care."

2. Needs model. This approach is based on a careful analysis of the problems encountered in practice and of the knowledge required to solve these problems. Such an analysis yields a physician-specific profile that can be used

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[a] This section draws heavily on material by the author previously published elsewhere (*29*).

as a *starting point for tailor-made remedial education*. Perhaps the best-known example of this approach is the programme implemented by the University of Wisconsin (*120*), in which the problems are identified by recording for one day, over a four-week period, the characteristics and problems of all patients. The providers are tested on the most important problem areas of their own practice. A special educational consultant then helps the providers to choose from a computerized educational resource file those educational experiences that are best suited for their needs.

3. Educational outreach. In this approach, the starting point is a problem area that is considered to be important. To solve this problem, a special effort is made by exposing the providers to various educational experiences, including visits to their practices by educational consultants. The executor of such a programme can be a national or state medical society, a health authority, or a voluntary association. The method can be quite effective in the case of new treatment methods, diagnostic tests, or a health problem often neglected by the providers. It can also be fairly cost-effective. The main problems are related to the relevance of the selected problem to the actual practice of the majority of providers. If it is not considered to be relevant, motivation can be low and, consequently, the results poor.

4. Situation model. In this approach, the provider's work setting is used as the teaching environment and experience. The method can be effectively used to teach new specific skills or to retrain personnel for specific purposes.

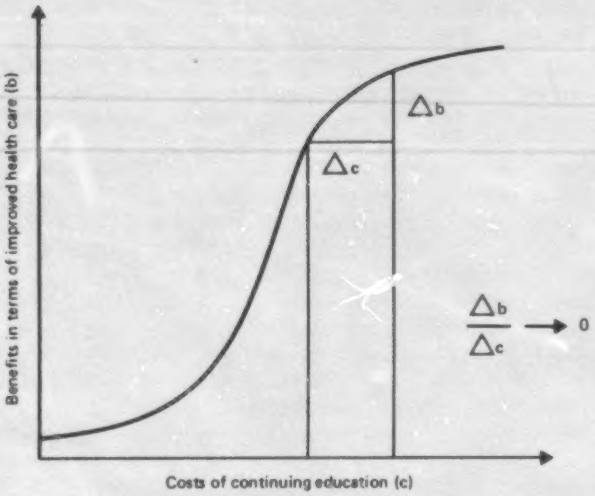
5. Data feedback. This approach is based on the belief that providing health professionals with data on their own performance and that of their peers will motivate them to improve the quality of their work. The results of such educational attempts have, however, been very mixed (*84,88,121,122*).

6. Linking education to analysis of performance. This approach is based on the bi-cycle concept discussed in detail later.

The bulk of current continuing education programmes belong to the first group. This certainly is the case in Europe, where the other types, often designed to correct some of the deficiencies of the traditional content approach, are virtually unheard of.

The basic weakness of the current approach to continuing education is its poor cost-effectiveness in terms of improved health care. Miller (*123*) has suggested that continuing education works on the upper plateau of an S-shaped curve. As a consequence, to use the terminology of economists, the marginal benefits of continuing education are very limited (Fig. 14). The investments in continuing education are tremendous: the direct costs of the programmes, the increased – and largely unnecessary – burden for the available teachers, the lost time on the part of providers, and their lost work output. The motivation of the trainees is often poor, which further decreases the benefit-cost ratio. Immediate retention of the learned material can sometimes be shown but long-term results are usually very discouraging, and persistent changes in the actual provision of care can very seldom be demonstrated.

Fig. 14. The cost-effectiveness of continuing education



Most continuing education programmes violate the principles of adult learning. They are not based on an analysis of the problems to be solved by means of education. They do not provide enough opportunities for feedback, nor for active learner participation. The prevailing mode of teaching is lecturing. If there are any educational objectives, they are vague and do not specify such features as accuracy, safety and time. As Brown & Uhl (*124*) have remarked, educators have continued to think of the physician in the same role model as their concept of the medical student – a receptacle for information and wisdom – rather than as a mature professional making critical decisions each working day of his life.

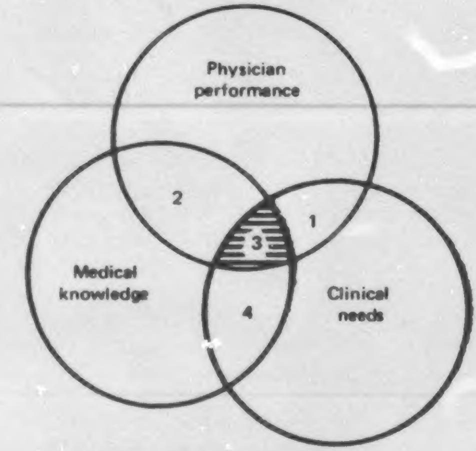
The usual approach to arranging continuing medical education has been categorical. Topics have been based on the research interests of academic teachers; recipients are seldom asked what they want and need. One cannot but agree with Storey (*125*) that "research interests of teachers are unlikely to be the most useful program determinants in the continuing education of practitioners, since the ever-changing interface between known and unknown is rarely the point at which the most profitable educational investment can be made".

There are also considerable organizational problems. The overall responsibility has seldom been defined. As a consequence, there is a multiplicity of sources with a concomitant great variation in the quality of programmes and in motivation for their arrangement. The funding of programmes is incoherent and the financial aspects that concern participants and their possible employers have not been solved. Because of unclear funding, the array of available programmes is shaped not only by an objective assessment of needs but by market forces. Nonsaleable or unprofitable subjects are often neglected in spite of their great potential relevance to the problems of everyday practice. Three alternative solutions have been suggested to such problems. The representatives of one school of thought completely deny the value of formal continuing education and claim that the solution is a critical approach to day-to-day clinical work and ensuing free discussion among colleagues about experience thus gained (*101*). According to the second school of thought, the present weaknesses can be corrected by applying modern principles of adult education to continuing education and by gearing it to the practical needs of professionals. For protagonists of the third approach, the solution lies in making continuing education mandatory to every physician so as to guarantee that even the black sheep will be exposed to its beneficial influence.

One of the clearest lessons from analysis of the weaknesses of current continuing education is that the best way to increase the benefit-cost ratio is to concentrate scarce resources in areas with large potential "pay-off" in patient care improvements (*34*). This idea is basic to the bi-cycle approach which gears remedial action to observed deficiencies by means of quality assurance. Storey (*125*) has analysed the priority areas for continuing education in terms of actual physician performance, available medical knowledge, and clinical needs. Fig. 15 illustrates their interrelationships.

From the point of view of continuing education, interfaces 2 and 4 are of interest. The majority of current continuing education programmes fall under interface 2, whereas interface 4 is the area that would really need educational remedies. It is an area where the necessary knowledge needed in care is available but is not being used by the providers. Even within this area, a more detailed analysis is needed to make continuing education really effective. For this, various priority setting mechanisms have been suggested.

Fig. 15. The interrelationship of physician performance, medical knowledge, and clinical needs



On the surface, the opinions of the providers on the most important problems they encounter would seem to be a good basis for priority setting. Brown & Fleisher (*34*) found, however, that when requested to list what they thought were the 10 leading causes of disability in the patient material of a hospital, an average staff member guessed correctly only 2 or 3 of the objectively determined priorities.

Although the bi-cycle concept is one of the most promising avenues for improving the quality of care, a dissenting viewpoint should also be presented. Osborne (*126*) interviewed the medical audit committee chairmen in each of the 70 general hospitals in central and southern Illinois. While 81% of the chairmen believed audit was a good method of planning continuing medical education, only 23% could identify a continuing education programme that had actually been developed from audit. Osborne concludes that, even though it appears theoretically sound to base formal continuing medical education programmes on needs identified through medical audit, those most directly involved in audit at the local hospital level in central and southern Illinois do not perceive this to be a workable method. Continuing education is also a remedy that comes *ex post facto* and does not benefit the patient that may have suffered because of a provider's deficient performance. Barnett et al. (*88*) claim that this objective can be achieved by means of concurrent monitoring only. Concurrent monitoring, in turn, presumes an information system that immediately detects deviations from the boundaries of acceptable care.

European experience

Typical internal quality assurance methods comprise tissue committees, clinicopathological meetings, checking of medical records, treatment protocols, and medical audit.

The few existing tissue committees have emerged as the result of professional initiative. The value of pathological confirmation of diagnoses is generally acknowledged and all countries encourage – some require – the sending of a sample of surgically removed tissue to a pathologist. In many countries the lack of trained pathologists is the main obstacle to instituting tissue committees.

Clinico-pathological meetings are common in all larger, especially academic, hospitals. In Czechoslovakia they are mandatory when there is any reason to suspect that a patient has died as a result of a medical intervention. The selection of topics, however, is usually based on their scientific interest, not on their contribution to quality assurance. Clinico-pathological meetings are obviously much more important vehicles of continuing education than of quality assurance. They are perforce an unsystematic, piecemeal approach to assessing the quality of care.

Checking of medical records by senior physicians is a relatively common procedure. Before a record can be stored after the discharge of a patient, a senior physician checks it for the appropriateness of the diagnosis, concordance of findings and therapy, and follow-up. This approach is usually based on implicit rather than explicit criteria and standards. Consequently, both its educational and quality assurance values are limited.

Treatment programmes[a] seem to be a typically European approach to quality assurance. They can be defined as sets of recommended guidelines for measures to be taken by different categories of health personnel at different levels of care in the prevention, diagnosis, treatment and rehabilitation of a patient with a given health problem. They are extensively used in the socialist countries and they are currently being developed and experimented with in the Scandinavian countries. In the socialist countries, they consist of methodological directives issued by the national health authorities, the national institutes representing different medical specialties, or the scientific advisory bodies to the health authorities. Usually, a methodological directive deals with some important current topic, such as the treatment of hypertension or indications for using a new drug or a diagnostic procedure. For this reason, they are not necessarily very systematic in the sense that they would cover the entire spectrum of the care of a disease from prevention to rehabilitation.

The Swedish and Finnish approaches to treatment programmes are particularly interesting as they clearly reveal the underlying motivation. The objectives of the Swedish programmes are as follows:

- integration of health services within the care system (by clearly defining the role of various health care institutions and provider groups)
- provision of comprehensive care (by explicitly listing all the activities in the process of care at a given level)
- increased efficiency of services (by eliminating duplication)
- integration of health and social services
- education of health professionals (by providing comprehensive guidelines and models of good care)
- improved communication
- provision of decision-making criteria for politicians

In Finland the objectives are:

- reduction of duplication of services
- shortening the length of stay
- increased safety of the patients
- increased protection of the providers against litigation
- provision of a planning tool to estimate the resources needed

In these objectives, efficiency seems to be the overriding concern but the programmes can, of course, be used as yardsticks against which the care actually delivered can be measured. It should, however, be pointed out that the health authorities and the representatives of the medical profession who have worked on these programmes have been very careful to make it clear that the programmes are only recommendations and in no way constitute norms. As a consequence, it is recommended that the guidelines be modified by actual users to correspond with the local conditions. The close collaboration of the health authorities with the medical and other health professions in the development of the programmes has resulted in their widespread acceptance. The outputs are comprehensive books covering epidemiology, etiology, diagnosis, treatment, follow-up and rehabilitation, as well as socioeconomic aspects of certain important diseases, and listing what different health professionals should – and should not – do at a given level or in a given institution in the care of a patient with one of these diseases. Some of the care programmes have been accepted as textbooks in either basic or specialist education.

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[a] Terms such as "treatment protocols", "care programmes" and "model health care programmes" are used synonymously with "treatment programmes".

The best example of external quality assurance is perhaps the control visits to health care institutions in the socialist countries. These are based on the health care system of these countries, which consists of several hierarchical levels whose number depends on the type of government and the size of the country, large federal countries having more levels. Each level has its own health care institutions, usually with well defined target area, target population, functions, staffing and equipment. These institutions range from health centres and polyclinics at the local level to the ministry of health and national institutes at the national level. Each higher level institution is in charge of all lower level institutions within its jurisdiction. This responsibility is divided according to medical specialties. Thus, the chief of surgery in a regional hospital is in charge of all surgeons in district hospitals and in polyclinics or health centres within the region. The primary care physicians are usually controlled by the higher level internists. The ministry has control over all jurisdictions and all specialties. The quality-related control functions at the national level are, however, usually exercised by the national institutes of health, based on medical specialties. These institutes may be service organizations (the most specialized care in a given specialty), purely scientific bodies, or advisory bodies to the ministry.

At the lower levels (e.g. local and district levels) the control visit is carried out by a single physician; at higher (e.g. regional and national) levels the visits can be made by special parties consisting of representatives of the specialty in question, nurses, social workers, and even physicists and chemists, depending on the type and extent of diagnostic and therapeutic equipment used by the lower level institutions. The visit of such a party may also concern the entire lower level institution, not just one of its specialty departments. In principle, the control function of any given level covers all levels below it. In practice, control is usually limited to the level immediately below that at which the *ex officio* controlling physician (i.e. the chief of a specialty), or the advisory specialist appointed for the purpose, works.

Before a visit, the institution to be visited provides the controlling party with the necessary statistical information pertaining to the process and outcome of care. The controlling party also has at its disposal all reports submitted by lower level control physicians.

During the visit, part of the time is devoted to examining the general working conditions of the institution (structure of the institution itself, demography and morbidity of the target population, etc.) and the actual functioning of the institution (number of services produced, resources used, length of stay, indicators of the outcome of care, and complaints filed by patients). The actual care is then reviewed; the latest methodological directives are often discussed and their implementation checked by reviewing patient records. The controlling physician may observe the actual functioning of the personnel of the institution. He may also visit the wards, examine patients himself, and compare his findings with those recorded by the treating physicians.

The outcome of the visit is a description and analysis of the situation and a list of recommendations. The recommendations may concern the structure of the institution (deviations from standards, acquisition of new equipment, upgrading the education of the staff), the administration, and the work of the health professionals (implementation of the methodological directives, errors or omissions in treatment, etc.). Before the departure of the controlling party, the recommendations are discussed with the persons concerned. The institution is given a deadline by which the recommendations have to be implemented. Punitive sanctions are rare. The public prosecutor is kept completely outside this control mechanism, any sanctions being professional, not legal. In extreme cases a health professional may lose his licence permanently or temporarily, and he may also lose a financial incentive to which he would otherwise be entitled. A more common recommendation is that the physician attend a refresher course. Also, rewards such as salary bonuses and special distinctions can be recommended for outstanding performance.

For the purposes of statistical quality assurance, most countries have a health information system based on discharge abstracts and routine statistics. The socialist countries make extensive use of this system in comparing the actual situation with established standards. A general limitation of many current health information systems is that they provide primarily data of the process output type, such as the number of services produced, where product output data (e.g. changes in the health status of the population) are required.

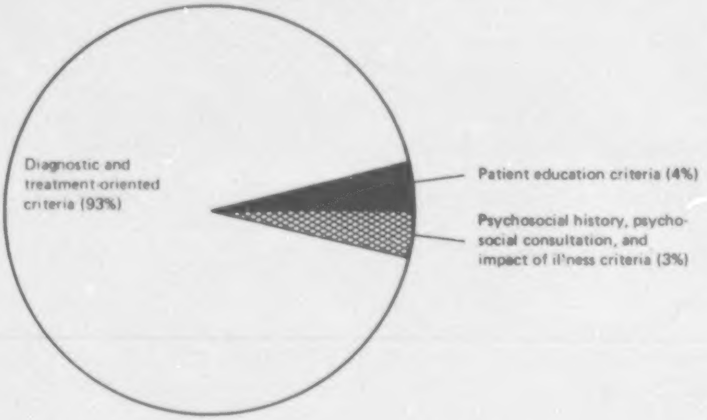
The drug prescription review used in Czechoslovakia, the German Democratic Republic and Yugoslavia is an example of a statistical, process-oriented quality assurance programme, mainly for administrative purposes. At the regional level, there are special pharmaceutical committees examining either all prescriptions or a sample of them. A manual or computer-assisted system produces various averages (e.g. by region, district, institution, medical specialty or drug) and physician-specific profiles that can be compared with the appropriate averages. The purpose is to detect both over- and underprescription. The prime motive is financial, but the system also increases the safety of the patient. In Czechoslovakia the committee tries to ascertain the appropriateness of individual prescriptions; in the German Democratic Republic only prescription patterns are monitored. Punitive sanctions are avoided if possible, the usual remedial action being a collegial discussion or a gentle reminder to draw the physician's attention to his deviant prescribing pattern.

Evaluation of the process approach

Some methods based on the process approach have established themselves. Nevertheless, strong criticism has been voiced against them. The most crucial argument is that the rationale of the entire approach is not justified. The results of studies on the correlation between process and outcome are somewhat equivocal. For instance, Kane et al. (*127*) found that in ambulatory care, in five out of the seven conditions they studied, there existed an overall correlation between good process, as measured by implicit and explicit criteria, and good outcome of care, as measured by restoration of functional status and patient satisfaction. Conversely, Fessel & van Brunt (*128*) found that there was a surprising disparity in the recorded data from hospital to hospital in the treatment of appendicitis. In spite of this the outcome, defined as a pathologically proved diagnosis, was the same from hospital to hospital. There was no significant relationship between the audit scores and any of the post-hospital outcomes for which records were examined in the case of acute myocardial infarction. The authors, however, do not completely deny the value of the process approach, but caution that it should not be used to evaluate an individual patient's record. It may be suitable for comparing groups of records of patients having the same condition of similar severity.

It has also been claimed that the data base of most process approach methods is invalid, since medical records do not necessarily give a true picture of what actually happened to the patient. Items that have been performed may be missing due to haste, negligence or because the results did not modify the course of treatment. The records usually only provide information on the cognitive aspects of care, i.e. those related to the level of knowledge of the provider. They do not tell anything about his attitudes, his psychomotor skill in performing operations, the acuity of his perception, or his analytical skill in interpreting and applying findings. Consequently, there is a strong tendency to develop criteria of good care only for those aspects of care which are known to be recorded. For instance, Berg & Kelly (*58*) found that out of the over 6000 criteria used in 448 medical audits completed in the Minneapolis-St Paul area from 1975 to 1979, some 93% were related to diagnosis and treatment and only 3% to psychosocial variables (Fig. 16).

Fig. 16. Distribution of medical audit criteria concerned with various aspects of health care (N = 6662)



The problem-oriented medical record is partially immune to this criticism, since it has been designed to reveal the reliability, thoroughness, efficiency and analytical sense of the health professional. Weed (*91*) argues that there should be no rule in the audit relating to a physician's memory or store of memorized knowledge. This is in accordance both with the nature of medicine and with the expectations of patients. The physician is not expected to perform according to certain memorized criteria but logically in the context of a given patient. As a consequence, it is the logic of the physician that should be audited. This, according to Weed, presumes an individualized, case-oriented audit as opposed to general rules and criteria.

When applied rigidly, simply to anticipate the requirements of an audit, the criteria – especially explicit, detailed, disease-specific criteria – may constitute a straitjacket that blinds the provider to alternatives and may thus hamper the application of new and the testing of old knowledge. Defensive medicine, fostered by inappropriate audit mechanisms and fear of litigation, can contribute importantly to the cost explosion in health care.

In spite of this criticism, however, the process approach is probably here to stay. In a way, the process is the most invariable part of health care; the inputs and the outputs vary but the throughput of health care (although its exact content certainly varies) is always there, can be divided into components, and can always be studied. It is also clear that the process must have some bearing on the outcome, although the exact relationship is not always known.

A systems analysis view helps to identify the proper role of the process approach. In systems analysis it is customary to speak of process output (e.g. number of examinations performed) and product output (e.g. change in the health status of the target population). There is no question that the product output – the achievement of the objective of care – is the most valid measure of the quality (or rather utility) of care. The objective can be achieved by a set of means, which are usually hierarchical, i.e. a higher level mean is the objective of a lower level mean. This is the principle of the planning method known as goals-means analysis, often illustrated by means of a "relevance tree". In health care, the components of the treatment process constitute a hierarchy of objectives, sub-objectives and means. This notion is analogous to the chain of validity assumptions referred to earlier on p. 68.

As long as the objectives (product outputs) of health care have not been defined in a way acceptable to all, the process outputs are the closest approximation to the product outputs and, as such, a legitimate object of quality assurance. The usefulness of the various process outputs as indicators of the quality of care depends on the strength of the validity assumptions.

Criteria of acceptable treatment processes usually respond and can be made to respond more swiftly to medical progress than can structural or outcome criteria. It is difficult to get rid of an obsolete building, and it may take a long time to establish what the average expected outcome is, but a new diagnostic test or treatment can often be instituted almost instantly. This may naturally be undesirable if it lowers the logical quality of care but, this danger notwithstanding, the flexibility of the process approach is an asset. The tedious and time-consuming process of developing criteria of good care has sometimes been advanced as a drawback of the process approach. It may, however, be an asset since, provided the practitioners whose care is going to be assessed are involved, they will learn more about their own practice and develop a sound critical approach to their work.

The outcome approach

Rationale

The starting point of the outcome (end-result) approach is clear: as the objective of health care is to cure disease, arrest its progression, restore functional capacity, or alleviate pain and suffering, the success and quality of health care should be measured in terms of the achievement of these objectives. In addition, the prevention and avoidance of unnecessary complications belong to the desirable outcomes of health care. As long as the outcome is good, it is not so important to know by what means it is achieved.

This is the rationale of the outcome approach in its purest form. With the increasing emphasis on optimizing the quality of health services, a growing number of health service researchers as well as practitioners and administrators take exception to this notion. It *does* matter how the objectives have been achieved; for them, cost-efficiency is the important concern.

Origin

The first attempts to measure the quality of health services were based on the above rationale and employed the outcome approach. An early pioneer in this field was the French physician P.-C.-A. Louis who, during the first half of the 19th century, systematically studied the outcomes of various treatments. As he was more interested in the treatment *per se* than in its providers, his name is usually linked with the use of statistical methods in medicine and the development of clinical trials. Florence Nightingale propagated a uniform system for the collection and presentation of hospital statistics; she thought that they could be used to ascertain the results of various treatments.

Although the English surgeon E.W. Groves had already suggested in 1908 that the results of all operations be recorded and analysed, E.A. Codman, a surgeon working at the Massachusetts General Hospital, was the first to institute such a system a few years later. He not only recorded the immediate outcome of all patients on whom he had operated but he re-examined them a year later to ascertain the final outcome. He distinguished four factors influencing the outcome: the physician, the organization, the disease and the patient (*95*). Although Codman was not particularly successful in raising interest in this method among his colleagues, he received a grant to study hospitals with over 100 beds. Since his results were terrifying (only 89 out of 692 hospitals could be said to meet any reasonable standards for quality of care) the interest quickly shifted from the outcome approach to the structural approach so as to guarantee at least minimum standards (*83*).

Some of the reasons Christoffel (*111*) has advanced to explain Codman's failure are still valid today in analysing the resistance by the medical profession to the adoption of quality assurance.

1. At the beginning of this century, the leaders of medicine optimis[illegible]ly believed that progress in medical science would solve most problems related to unfavourable outcomes of medical care (i.e. the problem is one of science and of the state of the art, not one of the performance of the providers).

2. The Flexner report seemed to promise that improved medical education would provide a sound structure for high quality medical practice (i.e. problems would be solved by controlling the content of medical education and entry into the medical profession).

3. The medical profession was afraid of quality assurance, and it still considers quality assurance a threat to its independence.

4. Medicine was considered to be an art and hence not susceptible to quality assurance; this argument is still common.

5. The consumers of health services did not exert any pressure on the medical profession; today, the consumers want to make their voices heard and press hard for qualitatively adequate services.

Types of outcome

The outcomes used in connexion with quality assurance can be classified according to two axes: (*a*) were the outcomes observed after the care was given (*a posteriori*) or were they stated as expected outcomes in advance (*a priori*); and (*b*) are the outcomes common to all diseases (general) or are they disease-specific? Fig. 17 demonstrates the possible combinations of these four attributes of outcomes.

General outcomes (better health and lower mortality and morbidity) are primarily applicable if one wants to evaluate the quality of the entire health care system or of some substantial part thereof (e.g. maternal and child health care). They are usually too insensitive to tell one anything about the quality of care given by a provider although, for instance, the 5-year survival rate of all patients operated on by a surgeon might be used as a measure of the quality of care given by that surgeon. The example illustrates the impracticability of such measures in routine quality assurance: it takes a long time and a great number of patients to establish any meaningful figures and – perhaps worse – corrective measures come far too late. General outcomes are even more difficult to use in assessing the quality of care received by a given patient. One of the cardinal principles of evaluation is that the measure of outcome should be related to the objective of the activity: in health care, the objective is usually to solve the patient's specific health problem, consequently a specific outcome measure is needed.

The issue of observed *v.* expected outcomes is related to our knowledge of the natural history of the health problem and of the effectiveness of care in the treatment of this problem. If we know what we can expect in terms of health as a result of our intervention (if everything goes as it should) we can state in advance an expected outcome as a standard against which the

Fig. 17. Types of outcome of health care

		SPECIFICITY	
		General	Disease-specific
EXPECTED x OBSERVED	*a priori*	Improved health	Justification of diagnosis Discharge status Complications
	a posteriori	Morbidity Mortality Health status indices	Disease-specific mortality Complications Functional status

actual outcome can be compared. If such knowledge is lacking, we have to content ourselves with observing what actually happened and elucidating the reasons for the actual outcome should it be untoward, such as a death or a complication.

General outcome approach. The general outcome approach is very closely linked to the concept of health status indicators and indices. It was developed because it was felt that it provides the only possibility of studying the quality of a health care system as a whole and the best means of comparing various systems. It was also felt that the state of the art in medicine does not yet permit the development of specific and measurable outcome criteria for the treatment of most diseases. Should an overall evaluation of the health care system be based on those diseases for which specific and valid outcomes have been developed, the picture would, in all likelihood, be distorted due to a limited and biased sample. Furthermore, there is currently no logically tenable method to combine or compare the results of disease-specific quality assurance programmes so as to obtain an overall view. General outcomes are thus necessary.

General outcomes are expected or desired changes in the values of single indicators, or composite indices consisting of several indicators, that measure the health status of the population. Most often, they are used to obtain an idea of the quality of the total health care received by a defined population. Chen et al. (*129*) have suggested that a useful health status index should meet the following criteria.

1. The index must have direct normative relevance, i.e. it must reflect the values of society.

2. The index should be capable of being used in societal decision-making and priority setting. Changes both in the value and in the direction of the index have to be meaningful.

3. The index has to be sensitive to changes in the phenomenon it purports to measure.

4. The index has to consist of independent and identifiable components whose contribution to the total variation of the index is known.

5. The index should be capable of being constructed on the basis of currently collected data.

None of the currently used indices meets all these criteria. The development of a practicable health status index is limited by conceptual and methodological problems that cannot be treated here. It will suffice to mention some in order to illustrate their magnitude and complexity. What constitutes a health problem? Who defines it? How can different problems be weighed? What are the objectives of the treatment of a given problem? Whose objectives have the highest priority? How can the priorities be quantified? How can problems that occur at different ages be handled? How can consequences that occur at different times be handled? What consequences of a given problem should be included? How can the different consequences be weighed?[a]

The reasoning behind most indices can be illustrated by means of a model suggested by Rosser & Watts (*137*). The health of an individual (i) as a function of an illness can be described as a stream of morbidity states (M) between the onset of the illness (0) and the individual's recovery or death (s):

$$M_{i0}, M_{i1}, M_{i2}, \ldots, M_{is}$$

The treatment the individual receives can modify this morbidity stream. The treatment may result in each morbidity state (M′) being different and the point of recovery (t; $t < s$) or death (t; $t > s$) being different:

$$M'_{i0}, M'_{i1}, M'_{i2}, \ldots, M'_{it}$$

Should it be possible to quantify the inutility of each morbidity state for the individual, the difference between these two morbidity streams would be a measure of the utility of a given treatment for the individual. The reasoning can be expanded to cover all morbidity streams that an individual experiences during his lifetime. The difference between treated and untreated lifetime morbidity is thus an indicator of the value of health care for the individual. In actual calculation, the utility of prolonged healthy time and of postponed death should be taken into account. The next step would be to sum up the individual utilities so as to obtain an estimate of the total utility of health care for a given population.

Mortality, morbidity and discharge statuses are examples of commonly used general measures of outcome, although disease-specific morbidity rates do not constitute a general health status indicator. They can, however, be combined into a general indicator.

Mortality. Mortality is the oldest and perhaps most widely used measure of the health status of a population. It has, however, three major deficiencies: (*a*) diseases causing death account for only a small portion of the total morbidity; (*b*) mortality is insensitive to such qualitative differences as are usually measured in quality assurance; and (*c*) mortality is influenced by the age structure of the population. There is no way of circumventing the first weakness, although it has been claimed that the total mortality truthfully reflects the total morbidity of the population. The sensitivity of mortality as an indicator of health can be enhanced greatly by using either age-specific or disease-specific mortality rates. This, however, limits the scope of evaluation. The relative mortality (the proportion of all deaths to those of persons who die after the age of 50 years) (*138*) and standardized death rates solve the problem of age structure dependency, but not the other two weaknesses.

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[a] Readers interested in health status indices may consult the following review articles: Fanshel & Bush (*130*), Hennes (*131*), Goldsmith (*132*), Chen & Bryant (*133*) and Balinsky & Berger (*134*). Descriptions of currently used indices can be found in Berg (*135*) and in a special issue of the journal *Health services research* (*136*).

Mortality alone will hardly ever suffice to ascertain the impact or quality of health services. It may suggest that differences exist that are worthy of a closer look, but it is too crude a measure to provide guidelines for detailed priority setting and planning – let alone for assessing the quality of care given by a provider and for developing measures to improve his performance.

In many countries, physicians have been requested to assess the discharge status of a hospitalized patient by using scales such as "recovered – improved – no change – worse – dead". The reliability of this measure has been demonstrated to be virtually zero (*139*).

Disease-specific outcome approach. In its purest form the disease-specific *a posteriori* method presumes that the patient be re-examined by an evaluator, who should preferably be someone other than the original provider of care. In the ideal case, the re-examination should be repeated after a lapse of time within which the ultimate outcome, including the late sequelae of both the original problem and its treatment, is likely to occur. The purpose of this is to identify all possible treatment-related outcomes. These outcomes are then judged to be good or bad. The final step consists of comparing the outcome against the original treatment process so as to pinpoint the possible causes of the less than optimal outcome.

This method has great heuristic value: it can clarify the concept of quality; it can demonstrate unexpected relationships between factors determining quality of care; and it can suggest remedial actions beyond the conventional ones. Unfortunately, it is also very expensive and consumes a lot of evaluators' and patients' time. Consequently, it is very unlikely that anyone could afford to use this method routinely, but it can certainly serve as a valuable first step, a fact-finding and problem identification phase, in developing a more manageable and cheaper routine method.

Such a comprehensive *a posteriori* method also has a major practical drawback in that it either does not permit screening for those cases that require a closer analysis, or makes such screening very cumbersome. In each case, extensive analysis is needed before one can decide that the outcome is so good that no further scrutiny is needed. Therefore, the next step towards a more structured and less resource consuming method consists of stating in advance outcome *areas* on which to focus. This permits some screening; if nothing alarming or otherwise interesting is found with regard to these areas, the case can be dismissed. The details and the rigidity of the expected outcomes can be increased gradually until one reaches the pure *a priori* approach with minutely detailed expected outcomes, standards for ascertaining their achievement, and exceptions that justify the non-achievement of the expected outcomes. The development of such outcomes is so tedious a process, that they are usually limited to a few really critical ones which are supposed to reflect the overall quality of the care. Such outcomes easily lend themselves to screening because there are only a few of them and the standards and exceptions are explicit; even a nonprofessional reviewer such as a record librarian or clerk can find out quickly which records need more detailed scrutiny. A major handicap of this approach is that unexpected phenomena go unnoticed.

Most methods that have been suggested for routine use are somewhere between the extremes, although closer to the pure *a priori* approach. Most of them ascertain the achievement of stated outcomes as a kind of screening device to single out cases that should be subjected to a more-or-less detailed analysis. They thus combine outcome and process approaches. They are true quality assurance mechanisms in the sense that their purpose is to identify and analyse problems so as to find appropriate remedial actions, be they educational, organizational or punitive. A couple of examples illustrate the principles of these methods.

Williamson and co-workers (*121,140–142*) have developed a method that they call "health accounting". The first step is to select the problem to be studied. They have developed an elaborate method for ranking problems, using such criteria as number of admissions, length of stay, complications, resulting impairment and its preventability, mortality, and associated social disruptions. To estimate the preventable impairment associated with the selected problems, they use both empirical standards (outcomes published in the medical literature) and normative standards (opinions of experts as to how much of the impairment could be prevented under ideal conditions). The actual assessment consists of comparing the observed outcome with the predicted outcome. If there is a difference, a detailed analysis of the treatment process is performed to find the cause of this discrepancy. This analysis, in turn, serves as a starting point for devising appropriate remedial actions, usually continuing education.

This method is resource consuming in both the planning and implementation phases; the development of standards involves, for example, extensive literature reviews and panels of experts. Furthermore, there are relatively few health problems for which unequivocal normative outcome standards can be developed. The inquiry into the causes of discrepancies between actual and expected outcomes is also costly and tedious. It requires a virtual re-enactment of the diagnostic and therapeutic procedure.

This method has evolved to a somewhat simpler one that Williamson (*143*) calls the structured quality assurance topic selection procedure. It uses the nominal group process and consists of five steps: (1) selecting and organizing the priority team, (2) training session, (3) incubation period, (4) priority meeting and (5) selecting topics for implementation. In its work, the priority team is aided by a check list containing items related to patient, health problem, provider and care interaction characteristics. The method has been tested in a large number of hospitals and group practices; it has been found acceptable for physicians and capable of leading to improvements in care. The users of this method emphasize its great motivational value and its relevance to the needs of practising physicians. According to the experience of Brown & Fleisher (*34*), once people have been responsible for defining a potential problem, they will take steps to diminish the problem.

Brook et al. (*144*) simplified the original health accounting method by using subjective judgement in selecting the problems to be studied. In a later, more methodologically-oriented study, Brook et al. (*2,78*) used such criteria as the extent to which medical intervention has an impact on the natural history of the disease, the frequency with which it occurs, the knowledge of non-medical factors affecting the natural history of the disease, and the availability of well defined treatment modalities for the problem. To select appropriate outcomes and set standards, they convened expert panels consisting of physicians with experience of various practice settings, epidemiology, and clinical research. Extensive literature reviews provided the panels with the necessary background for (*a*) defining the disease condition or operation to be studied and the relevant patient population; (*b*) identifying factors outside medical care having possible adverse effects on the outcome; (*c*) identifying the outcome concepts (including physical, physiological and psychosocial variables); (*d*) setting standards; and (*e*) identifying the points in time at which the outcome should be measured. The actual outcome was measured by medical record review and patient interview – considerably cheaper than the re-examination of patients used by Williamson et al.

The tracer method. The tracer method appears to be one of the most promising combinations of disease-specific process and outcome approaches to measuring the quality of care received by a defined population. Kessner et al. (*145,146*), the developers of the method, started by screening a defined population for tracer conditions (in their pilot study, anaemia, middle-ear disease, vision defects, and loss of hearing in children of various ages). Those with pathological findings were subjected to definitive medical examination. In addition, a separate sample of children who were registered with a health centre was studied. In the next phase, a survey was carried out to ascertain the usual practices of the local providers of services with regard to these tracer conditions. The records of a sample of children in the care of these providers were then studied to find out how these children had actually been treated and to ascertain the concordance of this treatment with pre-established minimal adequate criteria suggested by the providers themselves. Comparison of results points out the amount of missed diagnoses, the magnitude of the discrepancies between professed and actual behaviour, and the number of preventable poor outcomes.

A useful tracer has to meet the following criteria (*145*).

1. A tracer should have a definite functional impact. Conditions that are unlikely to be treated and those that cause negligible functional impairment are not useful.

2. A tracer should be well defined and easy to diagnose.

3. The prevalence rate should be high enough to permit the collection of adequate data from a limited population sample.

4. The natural history of the tracer condition should vary with the utilization and effectiveness of medical care.

5. The techniques of medical management of the condition should be well defined for at least one of the following processes: prevention, diagnosis, treatment or rehabilitation.

6. The effect of nonmedical factors on the tracer should be understood.

According to the developers of the method, criteria for the management of the tracer conditions should be characterized by the following: (*a*) they should outline minimal adequate care; (*b*) they should be pragmatic (take into account the availability of sophisticated diagnostic equipment); and (*c*) they should be revised periodically.

As the only population-based method, the tracer strategy is a valuable addition despite its high costs. It focuses attention on the functioning of the entire health care system, whereas most other methods only throw light on a limited episode of care. In countries with regionalized health services, with each provider having a well defined area of responsibility and target population, the contributions of the tracer method to health planning may be more significant than in the United States.

The tracer method may, however, have some drawbacks, particularly in primary health care. The tracer conditions that have been proposed so far refer to the management of diagnosed conditions, yet primary care deals in the first instance with undifferentiated symptoms rather than with clear-cut diagnostic entities. The second difficulty is that a set of indicator conditions might be put into use which missed completely the fact that every so often the symptoms brought to the primary physician do not represent the patient's underlying problem (*37*). A problem related to all care settings is that the use of tracers may lead to ostensible improvements in care: the providers, knowing the tracers, may improve their performance in the treatment of these conditions without changing their overall performance (*42,147*).

Evaluation of the outcome approach

The outcome approach is the most promising avenue to meaningful quality assurance: it is most relevant to the objectives of health care; it provides the most practical means of assessing the quality of care provided by a *system* and received by a defined *population*; it is not the only but probably the best approach to comparing providers; and outcomes are the starting point of all studies concerning efficiency. There are still quite a few wrinkles to be ironed out and some crucial questions are still unanswered. In medicine, it is not customary to state objectives and expected outcomes of care in a way needed for evaluation studies. The difficulties encountered by Brook & Avery (*148*) in developing outcome standards illustrate this point.

1. There is very little information available on average outcomes as opposed to optimal outcomes of medical processes and therapies.

2. There is very little information available on outcomes other than those related to physical and physiological variables.

3. Much of the conventional clinical wisdom on choice of outcomes and points of time at which to measure them is not documented.

4. Neither the natural history of many common diseases, nor the epidemiology of their outcomes, is well documented.

To these difficulties, one could add that often a short-term proxy measure has to be used, either because of deficient knowledge of what constitutes the ultimate outcome or because of the long time needed to obtain data on the ultimate outcome. Even with the best of intentions, it may be difficult to include psychosocial outcomes since either they are not amenable to measurement or they are so intertwined with other, uncontrollable variables that their independent contribution to the outcome cannot be ascertained. The outcome may also be an irrelevant measure of the quality of care, because the state of the art of medicine has not yet reached the point of being capable of achieving favourable outcomes (*149*). This argument is especially valid when using the outcome approach to monitor the performance of a health professional. It lends support to Weed's point that outcomes should only be used to measure the "goodness" of the system, not the performance of a provider within the system (*91*).

The difficulties of the outcome approach suggest that the natural history of diseases and conditions to be used as indicators or tracers be studied intensively, as well as the relationship between currently used therapies and actual and expected outcomes of care. Another lesson is that, in medical education, more attention has to be paid to stating precise and measurable objectives. The prognosis of an individual has been an important element in medicine since Hippocrates. The prognosis, often too vague and not taking into account the group characteristics of an individual, is usually not useful for the purposes of quality assurance. Two recent innovations seem promising in this respect. The problem-oriented record forces the physician to concentrate his attention on the problems of his patients and relate his actions to these problems. This implies setting problem-specific treatment objectives. Clinical decision-making trees also offer an alternative for systematizing medical care and relating diagnostic and therapeutic actions to an objective.

4

Methodological issues

SOURCES OF INFORMATION

A routine quality assurance system requires that the necessary data be collected quickly, conveniently and economically. Data collection should not rely on the use of health professionals, and the raw data should preferably be stored in one place. For the purposes of research, programme evaluation, fact-finding, problem identification and the development of a routine system, more elaborate and resource consuming data-gathering methods can be employed. The most common sources of information are:

(*a*) statistics and other data pertaining to the structure and organization of health care institutions;

(*b*) operational statistics of the health care institutions and of the providers of health services;

(*c*) medical records;

(*d*) participatory observation;

(*e*) opinions of the patients; and

(*f*) indirect (projective) methods.

The use of statistics is fairly straightforward, although their relevance to the assessment of the quality of care may be questionable and their interpretation difficult. Such statistics usually best serve the purposes of the structural approach.

Medical records

On the surface, medical records appear to be an ideal source of information, especially for the process approach. Each patient has his own record, which supposedly gives a truthful picture of his treatment. Especially in hospitals, these records are prepared using standardized forms and terminology and are stored in a central archive. Many hospitals use electronic data processing to store, analyse and transcribe some parts of the record, thus facilitating their comparison.

In practice, as sources of information for quality assurance, the value of medical records has been challenged. In most hospitals a fair share of the records cannot be found when needed. In spite of attempts to standardize them, they may be illegible and contain vaguely defined terms that vary from physician to physician. This is especially true in primary care and outpatient departments. The reliability of the medical record may be further weakened if the actual assessment of the quality of care is based on abstracts of the records. In a study conducted by the National Center for Health Services Research (*150*) it was found that gross error rates for abstracting and coding demographic items and dates of admission were low (less than 1%) but that gross error rates for principal diagnosis and principal procedure were high – about 35% and 20%, respectively. The private abstracting services offering their services to hospitals in the United States are not always able to maintain adequate quality control of the abstracts they produce.

The most fundamental criticism voiced against medical records as a source of information has already been referred to: they do not provide a reliable and comprehensive picture of the actual care. Because of these deficiencies, there is great danger that the object of quality assurance may turn out to be the quality of the medical record, not the quality of care given. Advocates of medical records, however, emphasize that a reliable and comprehensive record is an essential part of good care (*65*). According to Weed (*91*), no record can capture the entire medical reality, but the content of care revealed by the records is the only part that is being captured. Therefore, the quality of the record as an element of the overall quality of care can at least be used as a proxy measure of this larger concept.

Participatory observation

One of the charges against the use of medical records as a source of information in quality assurance is that not even the most perfect records will tell us all about the doctor. They cannot easily convey the warmth, kindness, empathy and consideration that a good doctor exhibits, and which are particularly important in primary care. Direct observation seems the best way to do this (*42*). Participatory observation permits direct data gathering the moment something happens, and the method is therefore most applicable in the process approach. A prerequisite of this method is the development of clearly identifiable and mutually exclusive observation categories. This requirement is seldom fulfilled although, for instance, the Royal Australian College of General Practitioners is developing a protocol for participatory observation, which includes a rating suitable for recording a physician's performance – preferably by his peers. Provided that minimum requirements concerning reliability are met, the method may be a very useful tool in an exploratory and descriptive study aiming at problem identification and fact-finding. The high costs of developing the measuring instrument (a protocol of observation categories and their application), of training the observers, and of the observation itself probably preclude the routine use of this method.

Opinion of the patient

It has often been claimed that one of the characteristic features of health care as an economic system is the consumer's ignorance of the true value and quality of the services he uses (*151*). However, there is a growing awareness of the importance of customer satisfaction as a determinant of high quality care. This trend is enhanced by the participation and interest of people in the provision of services while they are healthy, i.e. when they are not patients but consumers (*152*). Patients are often in need of immediate help and in too weak a condition to scrutinize the services they receive, whereas the consumer has a very different view of health services. He knows that his money – either in the form of taxes or insurance premiums – is used to finance health services. With prepaid health services, he pays for his services in advance; he may even belong to a group that has been formed for the express purpose of buying health services. As a member, his chances to influence the health care system are greatly enhanced.

WHO has acknowledged the principle of consumer participation. It is one of the cornerstones of the Declaration of Alma-Ata (*44*) which also lists "social acceptability" among the characteristics of primary health care. Earlier, the approach was through health education. It was emphasized that greater efforts should be made to educate the community on health matters (*153*) and that patients should be fully informed about the health services available (*154*). This perhaps somewhat paternalistic approach has led to the principle of full participation by consumers in the planning and running of health care (*155,156*). Consumer participation is now one of the main directions of the WHO European programme in primary health care (*157*). A parallel development has been the increasing emphasis on consumer satisfaction as a component of quality (*158–160*).

Several studies have demonstrated that consumers have increasingly sophisticated qualitative criteria concerning the care they receive. These criteria may emphasize aspects that the professionals deem unimportant or even irrelevant for high quality. This is natural, because providers and consumers have different implicit and explicit objectives that are not necessarily symmetrical or reciprocal (*37*). In spite of this, the satisfaction of the patient is an essential qualitative criterion of the medical encounter. Furthermore, there is evidence that criteria used by consumers often coincide with those used by the professionals. Vuori et al. (*72*) found that ambulatory patients used instrumental criteria (i.e. factors related to the scientific-technical aspects of care) very much in the same way as the professionals in assessing the quality of care they had received.

Studies related to consumer satisfaction may be particularly important in primary care. As Horder (*56*) has noted, acceptability and satisfaction matter at all times, but even more so when a cure or effective intervention are not possible or needed because of insoluble or self-limiting problems, which is often the case in primary care. The usual method of gathering patient opinions is the survey, but complaints filed by patients can also be studied.

Indirect methods

Social scientists use indirect, often projective, methods to study attitudes and characteristics that cannot be studied directly because of methodological difficulties or resistance on the part of the persons to be studied. This approach has been used primarily in attempts to develop models of good care, or in assessing the quality of care when it has not been possible to obtain an adequate sample of actual care given (such as a very heterogeneous group of patients or a young provider with limited experience). The subjects were presented with a hypothetical situation and requested to describe how they would behave in that situation. Modified sociometric methods were used in which subjects were requested to identify the physician to whom they would turn when sick. It was assumed that the characteristics of physicians that received the most "votes" constituted the prototype of a good physician.

CARE TO BE ANALYSED

The actual care (i.e. a set of health services) to be subjected to quality assurance can be defined on at least three bases.

1. *Persons or institutions.* We may be interested in:

    - care received by patients;
    - care given by providers; or
    - care given in various medical care settings.

2. *Health problems.* We may be interested in care given in connexion with:

    - a diagnosis; or
    - a health problem experienced by the patient.

3. *Operations and procedures.* Our interest may focus on surgical operations or high-risk diagnostic and supporting procedures, such as heart catheterization, blood transfusion or anaesthesia.

The bulk of quality assurance concerns care given by certain providers, because this is the area where the greatest variation occurs and where various remedial actions are most effective. The other delineation bases have often been used in more theoretically oriented activities or to reduce the assessment of the "care given by a provider" to a manageable task. There are two schools of thought in this respect. According to one, all care should be subjected to quality assurance but, if this is impossible because of logistic or economic reasons, a *probability sample* of all care should be scrutinized. According to the other view, it is not even in principle desirable to strive for total coverage because of the low yield of instances of poor care; therefore a *purposive sample* is needed. Resources have to be concentrated on areas where one may expect higher benefits because of a gap between the achievable and the actual. The search for such areas of care can be guided by the following factors.

1. *Factors related to the receiver of care.* The care received by a geographically or administratively defined population, by those acutely or chronically ill, by the very young or the very old, by the rich or the poor, etc. can be subjected to special analysis.

2. *Factors related to the provider.* The newly graduated or those approaching retirement age can be considered to be in need of special attention. Previous quality assurance or frequent patient complaints may indicate that the care given by a certain provider or in a certain health care institution should be monitored constantly. Certain working environments may be conducive to great variation in the quality of care, justifying more intensive or extensive quality assurance than more stable working conditions.

3. *Factors related to the health problem.* The consequences of poor quality care may differ according to the health problem. Such factors will be considered in detail below.

4. *Factors related to the type of service.* The decisive factor is the likelihood of poor quality care causing serious consequences. Anaesthesia, complicated operations, blood transfusion, etc. may deserve more attention than more trivial diagnostic and therapeutic interventions.

When a health problem or diagnosis (point 3 above) is being used as a selection criterion, the following considerations may help to identify the most appropriate focus of quality assurance (*8,22,145,148*).

1. *High prevalence of the problem.* A relatively small population sample should yield enough cases for statistical analysis; the providers should encounter the problem often enough to establish a pattern.

2. *Identifiability of the problem.* A pattern can be discerned and comparisons made only when the problem under scrutiny can be reliably identified (diagnosed).

3. *Significance of the problem.* The management of self-limiting problems does not warrant study. The problem should preferably be a serious one.

4. *Amenability to medical intervention.* The study of a problem upon which medicine has no impact is not warranted. The problem may, however, have other dimensions, such as patient satisfaction, which may depend on the management of the problem even though the medically defined outcome does not (e.g. terminal care). Such problems are naturally legitimate objects of quality assurance.

5. *Natural history of the problem.* The natural history should be known so that factors outside medical care, but influencing the outcome, may be controlled.

6. *Costs of care.* The more costly the management of the problem, the more suitable it is as a subject of quality assurance.

7. *Existing variation in the quality of care.* If it is known or suspected that there is considerable variation in the management of the problem, quality assurance is warranted.

8. *Severity of the consequences of poor quality care.* If the care – even when it clearly deviates from established and accepted standards – has no, or only negligible, deleterious consequences for the patient, there is no particular reason to waste resources on quality assurance.

9. *Possibilities of improving the quality of care.* The problem should be such that it is possible to devise a meaningful and effective corrective action on the basis of the assessment.

The method of Williamson et al. (*140*) is an example of a sophisticated technique to select health problems for scrutiny. Their purpose was to rank medical conditions according to the extent of associate patient impairment. Expected impairment was calculated by multiplying a disability weight (based on length of stay, complications and death) by a social disruption weight based on age. The resulting totals were then distributed among the discharge diagnoses, the largest portion being assigned to the primary diagnosis and progressively less to the second, third and fourth diagnoses. The weights, assigned to each diagnostic category from all patients discharged, were then totalled and the diagnoses ranked according to their cumulative total priority weight.

SAMPLING

To sample or not to sample, that is the basic question. The answer depends on the objectives and on how the care to be studied has been defined. For the purposes of "pure" research, policy planning and programme evaluation, a sample is virtually always sufficient, whereas guaranteeing minimum standards and the protection of consumers by concurrent monitoring require total coverage. Screening for fraud requires total coverage of a subpopulation, i.e. those suspected of producing poor quality services. Some health problems, operations or procedures can be considered to be so important that a 100% sample is needed.

The most frequent question concerning sampling is whether all services produced by a certain professional should be analysed, or whether a sample will suffice. The answer depends on the "philosophy" of the assessor. Some claim that all care should be subjected to assessment to catch all mistakes, and that each deviation from an accepted standard should be recorded and acted on. Others are of the opinion that quality assurance should be concerned with patterns of care, not with isolated incidents of unsatisfactory care unless they constitute gross negligence (*8*). For pattern recognition aiming at preventing future mistakes, sampling is usually sufficient. The sample has to be large and representative enough to give a reliable profile of the provider's performance. This profile serves as a basis for planning remedial action (*100*).

When sampling is considered adequate, the objectives of quality assurance determine the levels at which sampling takes place. For instance, the objective of "pure" research may be to find out the average level of care given by various health professionals in various institutions. In this case, a multistage sampling procedure can be applied: first the institutions, second the professionals, and third the care given by them.

Indicator diseases and the structural approach are two special cases of purposive sampling. In the first, one has to find diagnostic categories or conditions that are typical of a given medical specialty or an institution, and that reliably reflect the overall quality of care. Typical examples of indicator diseases and conditions are myocardial infarction and bronchial asthma in internal medicine, appendicectomy and cholecystectomy in surgery, and hysterectomy and Caesarean section in gynaecology. In this sampling, or rather selection, the guidelines and systematic weighting techniques described above can be used.

In the structural approach, there is a similar selection problem. We are interested in the potential for a provider to produce high quality, and this is measured by means of those structural properties of the provider that are known or assumed to be related to the outcome of care (e.g. training, equipment and management). To make the measurement manageable, reliable and valid, structural properties having the highest correlation with the outcome of care should be selected. Since these correlations have usually not been ascertained (i.e. the validity assumptions between structural properties and outcome have not been tested), the selection is perforce rather arbitrary.

CRITERIA AND STANDARDS

Quality assurance consists of two components, measurement (assessment) and policy (remedial action on the basis of the findings of the assessment).

The measurement also has two components, the one objective (the application of a yardstick to the phenomenon to be measured) and the other subjective (the establishment on the yardstick of a point that should be reached). The yardstick itself is the *criterion* of good care. It is a typical measuring instrument and, as such, has to meet all the customary requirements: validity, reliability and sensitivity. Each criterion has a scale, which can range from a nominal scale (yes – no) through an ordinal scale (very good – good – average – bad – very bad) to an interval scale (1, 2, 3, . . ., n). For each criterion a point on the scale has to be agreed on, above which the particular aspect of care measured by this criterion is considered to be good (acceptable) and below which it is considered to be bad (unacceptable). This point is the *standard* of care on this criterion. For example, the criterion can be the taking of a chest X-ray of hospitalized patients. This criterion has a scale consisting of two values: yes and no. The standard can be established either for each individual patient or for all patients. In the former case, the standard has to be one of the actual values on the scale (in this case probably "yes"); in the latter case, the standard is some agreed frequency (such as 80%) with which the criterion has to be fulfilled.

Criteria of good care

The criteria of good care can be classified according to three main dimensions: they can be either implicit or explicit; they can be either general or disease-specific; and they can be either ideal or empirical (*4,5*).

Implicit v. explicit criteria

The use of implicit criteria means that the assessor of the quality of care, usually an expert, poses to himself the question, "what would I do in a similar situation?". Clearly, the reliability of such an assessment is poor, and consequently the use of implicit criteria is waning. Explicit criteria are stated in advance. This enhances the possibility of using them consistently; in any case, inter-observer variation in the use of such criteria can be ascertained. Consequently, the comparability and reliability of the assessments are much better than is the case with implicit criteria.

The Scandinavian treatment programmes and the methodological directives of the socialist countries are good examples of explicit criteria. These constitute models of good care that can be employed both in actual treatment and in evaluating this treatment. Interestingly, in Czechoslovakia such models were used some 20 years ago but were abandoned; since then, only implicit criteria have been used. Now, with the increasing complexity and cost of care, there is a renewed interest in the development of explicit models as their use is believed to be conducive not only to high quality but also to efficiency.

The control visits to health care institutions characteristic of the socialist countries offer an interesting example of a combination of implicit and explicit criteria. While checking compliance with structural standards, the controlling physicians use very detailed explicit criteria. In reviewing the actual care given, they partly compare recorded care against the explicit model supplied by the methodological directives, and partly use their own judgement when examining patients and observing the work of the health professionals. The health authorities are convinced that the uniform education and high-level expertise of the controlling physicians effectively guarantee the reliability and comparability of the results obtained with implicit criteria.

Disease-specific v. general criteria

There are two schools of thought concerning the relative merits of general and disease-specific criteria. According to one, only disease-specific criteria are objective and specific enough to provide reliable and comparable information. Such criteria are also more in line with the nature of a physician's work and the concept of quality assurance. The criteria constitute a model of good care. According to the advocates of disease-specific criteria, each disease constitutes a separate model since the symptoms, appropriate diagnostic tests and therapy vary from disease to disease. Consequently, criteria have to be disease-specific.

The proponents of general criteria claim that disease-specific criteria draw attention to minute details of care that are often irrelevant to its outcome. Such criteria may also stifle innovative care. According to them, general criteria draw attention to truly critical incidents in patient care. Examples of general criteria include exceptional medical events (such as revision of previous surgical procedures, or anaphylactic shock), iatrogenic incidents (such as medication errors, patient accidents, or hospital infection), length of stay, and changes in the health or functional status of the patient.

The argument between the protagonists of disease-specific and general criteria follows closely that between advocates of the process and outcome approaches. Disease-specific criteria are more appropriate for process analysis, whereas in outcome analysis general criteria may be more useful. The use of disease-specific and general outcomes has been discussed earlier.

Ideal (normative) v. empirical criteria

In the true sense of the word, ideal criteria presume that we know in absolute terms what constitutes the best possible care. The components of a model of the best possible care are our ideal criteria. Since medicine is not static, the identification of truly ideal criteria is utopian. Therefore, the current medical knowledge and technology (as expressed in textbooks, in scientific articles, and by leading experts) is used as the ideal model on which to base the actual criteria. In theory, it would be possible to check the actual care given against the entire ideal model by using a very comprehensive set of criteria, but in practice this is not feasible. Therefore, a few indicator criteria have to be selected on the basis of their importance or representativeness.

Empirical criteria are those selected on the basis of previous practice. The problem with these is that practices exist that are based on conventional wisdom and are irrelevant to the objectives of care. The unquestioning translation of such practices into criteria of good care can thus actually lower quality.

The distinction between ideal and empirical criteria is relatively unimportant, certainly less important than a similar distinction between ideal and empirical standards. In most instances, the researchers or executors of a quality assurance scheme first assemble a panel of experts to develop the criteria of good care, i.e. a set of ideal criteria, but the next step often consists of adjusting these criteria to correspond with local conditions.

The adjustment of the criteria to the local situation may be one of the keys to successful quality assurance. It has been recommended that the health professionals whose activities are to be scrutinized should themselves be responsible for the entire quality assurance process, or at least participate therein, because of its great educational value. Local responsibility and participation would also result in more meaningful criteria. Dissenting opinions have, however, also been voiced. Lembcke (*115,116*) claimed that the objectivity of the criteria presumes that they be universal and based on the opinions of leading experts. These two views are not necessarily mutually exclusive. For instance, it has been demonstrated that specialists working in non-teaching hospitals (*161*) and local practitioners (*162*) developed sets of disease-specific criteria that were very concordant with those developed by teaching hospital specialists.

General requirements for acceptable criteria

The requirements that have been set for criteria vary and may even be contradictory (*35,83,117,159,163*):

(*a*) objectivity (stated in writing precisely and in detail);

(*b*) verifiability;

(*c*) comprehensiveness;

(*d*) universality (the criteria and their application should not depend on the health care institution, patient mix, and other similar factors);

(*e*) disease-specificity;

(*f*) pertinence (the criteria should be related to the objective of care);

(*g*) ease of use;

(*h*) sensitivity; and

(*i*) acceptability (conforming with generally accepted notions of high quality care).

There is often a tendency to apply too many criteria, which makes the assessment part of the quality assurance a costly and time-consuming process. To counteract this tendency, Lewis (*83*) suggests that the following questions, applicable to process analysis, be asked with regard to the proposed criteria.

1. What is the necessary data base to make a diagnosis "x"?

2. Which of these criteria are needed to establish 99% of all diagnoses of "x", *v.* those included in order not to miss the 1% or less that are "atypical"?

3. Which of the criteria are included in order to look for underlying causes of "x"?

4. Which of the criteria are included to identify possible complications of "x"?

5. What criteria are being used to anticipate the use of certain drugs?

6. How many of the criteria are listed because either the patient or the referring physician expects a prestigious institution to do these things?

7. How many of the criteria are included because of a need to practise defensive medicine?

8. How many criteria represent items done for teaching value or because of the clinical mentality of the providers?

The point is clear: a great number of the commonly suggested criteria – and health services – serve other purposes than improving the quality of care. Consequently, should it be possible to weed out such criteria the practicability of quality assurance could be enhanced greatly. A related problem is the inability of any list of criteria to simulate adequately the decision-making process of a physician. As Greenfieid et al. (*164*) have noted, the physician, in caring for the individual patient, collects certain data and takes action on the basis of the data already collected. The medical care process is conditional – not all things are done for all patients with the same disease or complaint. The single explicit list, intended to be applied to all cases of a specific disease or diagnosis, fails to account for this.

Standards of good care

A standard is the value on a criterion that indicates the boundary between acceptable and unacceptable quality. Usually, we are only concerned with minimum standards, i.e. things that should have been done in the course of treatment. If we accept the concepts of optimal and logical quality, we have to accept the possibility that doing too much also constitutes substandard care. This point primarily applies to the process approach, but also the structure can be unnecessarily good in relation to the objectives; an outcome can perhaps never be too good. Helfer (*165*) has suggested two concepts to cover these aspects. *Proficiency* tells us whether everything considered necessary in good care was really done, whereas *efficiency* indicates whether everything that was done was really necessary:

$$\text{Proficiency (P)} = \frac{\text{Established criteria met}}{\text{All established criteria}} \times 100$$

$$\text{Efficiency (E)} = \frac{\text{Established criteria met}}{\text{All recorded criteria}} \times 100$$

For instance, if good diagnostic practice in a given disease is supposed to consist of 10 tests (all established criteria) and the medical record reveals that 12 tests (all recorded criteria) were performed and 8 of these are among the established criteria (established criteria met), the proficiency of that diagnostic procedure is $(8/10) \times 100 = 80\%$ and its efficiency $(8/12) \times 100 = 67\%$.

Proficiency is a measure of the conventionally defined scientific-technical quality of care, whereas efficiency primarily measures the logical quality. Since both are legitimate components of the overall quality of care, and the care given can be deficient with regard to both of them, they can be combined into a composite measure that may be called competence:

$$\text{Competence} = \frac{(P \times E/100) + P}{2}$$

The exact weighting of the two components of competence is, of course, a matter of convention.

Ideal (normative) v. empirical standards

An ideal standard means equating the acceptable performance with either the best imaginable performance (absolute ideal) or the best performance that is considered attainable under the best possible circumstances. When looking at the care received by a single patient, both alternatives lead to the same result: the standard has to be one of two values (+ or −; 1 or 0). The actual value depends on the type of criterion, whether it is something to be achieved (a favourable outcome) or performed (a diagnostic test) or avoided (a complication). If we are interested in the care received by several patients, the situation changes. The "absolute" ideal still allows only two possibilities: an average of 1 or 0 or a frequency of 100% or 0%. In the case of an "optimal" ideal, the standard is an agreed value between the two extremes. The basis of such an agreement can consist of expert opinions, results published in scientific journals, or results achieved in the best teaching hospitals.

Empirical standards are usually based on experiences gained in "typical" situations. They may be based on regional or national averages. Clearly, the dividing line between "optimal" ideal standards and empirical standards is vague. Empirical standards have been defended because they are supposed to provide a realistic target, in that they have been achieved in institutions not too dissimilar from the one in question. It can be frustrating to set standards so high that no one can reach them. Using empirical standards, comparison between institutions may help to identify means to achieve the standards.

From a practical standpoint, ideal standards may even be harmful. Health care institutions and providers may unnecessarily try to achieve them and to emulate institutions that have been charged with more demanding responsibilities. Paradoxically this may lower the scientific-technical quality of the emulating institutions, since a smaller population base may not enable them to maintain the necessary technical competence, even though the resources may be available. Furthermore, the logical quality of care and the overall efficiency of the entire health care system may be lowered if resources are allocated to institutions in which they cannot be utilized effectively. For such reasons, it has been argued that the standards should be developed locally or, at least, adjusted locally.

Empirical standards also can be counter-productive. They may encourage mediocre care and perpetuate established bad treatment habits. The most important limitation of empirical standards is that they may conceal actual poor performance even though the standards have been achieved. Empirical standards are usually averages, which can result from countless combinations of actual observed values. Sometimes an observed poor value may be completely justified by the circumstances but, by looking at an average, there is no way of telling how the average emerged.

Jacobs et al. (*8*) have solved this problem by defining a criterion of good care as follows:

Criterion = Element + Standard + Exceptions

In their terminology, the element is the actual yardstick (i.e. the criterion in the sense used in this book and by most authors). They have three objectives: to set a standard that (*a*) enables rapid screening for poor performance by a non-professional person; (*b*) renders the meaning of an average unequivocal; and (*c*) reduces the amount of professional time needed to study justifiable non-achievement of standards. These objectives can be achieved by means of a combination of "absolute" ideal standards and pre-established legitimate exceptions for not achieving the standards. When examining the medical record of a patient, the person in charge of this process has first to determine whether the standard has been achieved or not. Since there are only two possible values (1 or 0; + or −), this screening for unacceptable performance is simple, fast and reliable. The second step consists of checking for legitimate exceptions in the case of possibly unacceptable care. Should such an exception exist, the record can be reclassified as acceptable care. Since the exceptions are pre-established and can be explained in great detail and clarified by examples, even this step can be entrusted to a non-professional person. Consequently, the professionals in charge of the actual audit can concentrate their efforts on those records really in need of closer scrutiny. Finally the resulting averages, all instances of non-achievement of the standard and true indications of substandard care, can be used as indicators of the quality of care and to compare individual providers, groups of providers or institutions. According to some critics, however, this approach may be too rigid and does not motivate the practising physician.

Both types of standard are used in Europe, and the selection of one or the other seems to a great extent a matter of expediency. The ambitious, scientific standard-setting approach used in the Soviet Union and emulated in many other socialist countries illustrates this. The Soviet authorities speak of factual (empirical) and prospective (ideal) standards. The prospective standards are based on the health needs of the population, the factual ones on an accurate assessment of the current situation. To establish the standards, three sources of information are available: (*a*) routine statistics and progress reports submitted by the health care institutions, covering primarily the mortality and morbidity of the population as well as the production and utilization of health services; (*b*) *ad hoc* studies dealing with important specific problems; and (*c*) decennial morbidity surveys.

Prospective standards are based on morbidity surveys and represent the scientifically determined optimal situation, whereas factual standards are regional or national averages, or averages by type of institution, medical specialty, etc. In a way, the achievement of a factual standard can be considered a milestone on the way to achieving the relevant prospective standard. Routine statistics and monthly, quarterly and annual progress reports permit comparison of the actual performance with the factual and prospective standards. The same approach is used in many countries, but its use is particularly widespread and systematic in the socialist countries of Europe.

The following formula, used in Hungary to determine the number of physicians needed, illustrates the scientific standard-setting characteristic of the socialist countries:

$$\text{Number of physicians} = \sum_{n=1}^{k} \frac{(p_x^f \cdot v_x^f \cdot t_x^f) + (p_x^m \cdot v_x^m \cdot t_x^m)}{60dw}$$

where v = number of visits per patient per year (combination of actual situation and expert opinions);
x = age groups;
p = size of population;
f = female;
m = male;
t = duration of visit (minutes per patient);
d = average number of working days accomplished by physicians;
w = number of working hours per day; and
k = disease.

The actual values of the parameters are based on morbidity surveys (e.g. age distribution by disease), time and motion studies (e.g. average duration of a visit), and expert opinions (e.g. desirable number of visits per patient per year). The resulting standards are easy to use, both in planning and in the structural approach to quality assurance: according to the standards, in a given locality there should be *x* physicians whereas there are only *y*; patients with a certain disease are expected to see a physician *n* times a year whereas they see him only *m* times. Why?

The major limitation of such standards is that their validity assumptions have not always been determined.

Levels of standard-setting

A standard of good care can be set at four levels: (*a*) for a single criterion related to the care received by a single patient; (*b*) for a single criterion related to the care received by all patients included in the analysis; (*c*) for all criteria included in the analysis of the care received by a single patient; and (*d*) for all criteria related to the care received by all patients included in the analysis. Fig. 18 elucidates this idea, as well as the types of standard that can exist at the various levels.

At the first level ("one patient – one criterion") it makes no difference whether one uses ideal or empirical standards: one criterion for one patient can only have been met or not. At all other levels, "absolute" ideal standards mean that the standard is either a frequency of 100% or 0% or an average ($\bar{x}$) of 1 or 0. In the case of "optimal" ideal standards and empirical standards, the standard is some agreed average with which the criteria have to conform. Mathematically this notion can be presented as shown in Fig. 19. An example will serve to illustrate this idea. At the first level, we may set a standard that rectal examination has to be performed on every patient over 40 years

Fig. 18. Levels of standard-setting and types of possible standards at each level

	One patient	All patients
One criterion	1. Absolute and empirical: + or − 1 or 0	2. Absolute: 100% or 0% $\bar{x}$ = 1 or 0 Optimal and empirical: $\bar{x}$ = ? (agreed on)
All criteria	3. Absolute: 100% or 0% $\bar{x}$ = 1 or 0 Optimal and empirical: $\bar{x}$ = ? (agreed on)	4. Absolute: 100% or 0% $\bar{x}$ = 1 or 0 Optimal and empirical: $\bar{x}$ = ? (agreed on)

Fig. 19. The possible values of "optimal" and empirical standards

	One patient (k)	All patients (N)
One criterion (i)	1. $S = s_i$	2. $S = \frac{1}{N}\sum_k s_i$
All criteria (n)	3. $S = \frac{1}{n}\sum_i s_i$	4. $S = \frac{1}{nN}\sum_k \sum_i s_i$

S : standard

s_i : observed value on the scale of a criterion of age, i.e. the standard is 1 (or +). We do not accept any deviation from this. If we move our standard-setting to the second level, a provider's performance can be considered acceptable if he performs the examination on, say, 80% of all his patients over 40 years of age. At the third level, we may say that a patient has been appropriately treated if 80% of all the criteria applicable to his care have been met. Finally, at the fourth level, we may deem the overall quality of care given in an institution acceptable if the average compliance with all the criteria, in all the patients to whom the criteria apply, is 80%.

This may sound somewhat theoretical, but the level of standard-setting is relevant to two important issues: the objectives of quality assurance and the uses of quality-related research.

Uses of quality-related research

Fig. 20 illustrates the relationship between the level of standard-setting and the objectives of quality assurance. Standard-setting for a set of criteria (i.e. levels 3 and 4) may have little practical value but it can be used in theoretical studies. An example is the best way to illustrate this point. An investigator is interested in seeing whether patients' satisfaction with their care is influenced by socioeconomic factors within groups that have received qualitatively different care. To be able to correlate satisfaction with socioeconomic factors in such groups, he first needs to classify the care the patients have received so as to be able to assign them to a proper group. To do this, he sets a standard at the "all criteria – one patient" level; the care of a patient is "good" if 80% of all criteria that apply

Fig. 20. The uses of different levels of standard-setting

	One patient	All patients
One criterion	1. *Case study* Detection of all instances of poor quality	2. *Statistical analysis* Pattern recognition with regard to a criterion
All criteria	3. *Case study* Ascertainment of overall quality of care received by a patient	4. *Statistical analysis* Ascertainment of overall quality of care received by all patients

in his case have been met, "bad" if the compliance rate falls below this. Similarly, a standard set at the "all criteria – all patients" level could be used in studies comparing health care systems and correlating other system variables with the quality of care given.

These examples demonstrate that standard-setting at higher levels can be a convenient means of classifying care received by individual patients or patient groups – especially if one is content with a dichotomy consisting of acceptable and unacceptable care. In statistical analyses, the actual observed values (i.e. the frequencies of adherence to criteria) are naturally more useful since they contain more information.

METHODOLOGICAL PROPERTIES OF THE MEASURING INSTRUMENT

Each criterion is an instrument designed to measure some aspect of the quality of care. Giving a name to a measuring instrument entails a serious social obligation: it has to measure what the name implies in a valid, reliable and sensitive way (*166*). The obligations are especially binding when the measurement may result in sanctions against someone or have serious economic consequences, as in quality assurance.

Validity

Validity means the capability of a measuring instrument of measuring what it is purported to measure. The pragmatic (predictive) validity of a measuring instrument is related to its capacity to predict and discriminate. In quality assurance, we are primarily concerned with predictive validity. In more theoretically oriented studies conceptual validity becomes essential. It refers, for example, to the concordance of the concept on which a measuring instrument is based with related theory, and with other concepts derived from this theory.

The predictive validity of a measuring instrument can be established by comparing the results with some criterion. The value of this criterion should be obtained by means of some other independent measurement whose validity has already been established. The most natural criterion would be the phenomenon under scrutiny itself, such as quality, intelligence or speed. However, the "true" value of the phenomenon is usually not known – if it were, there would be no need for additional measurements. In quality assurance it is logical to compare the results obtained by means of outcome, process and structural approaches. Since the object of care is usually to improve the health status of the patient, the outcome approach comes closest to the "phenomenon itself" (i.e. quality of care) and its results can be used to validate the other two methods that are further removed from the objective. For instance, should good outcomes go hand in hand with such factors as highly trained personnel and modern equipment, the structural approach could be considered to be a valid method of measuring the quality of care.

Reliability

Reliability is usually defined as the ability of a measuring instrument to measure in a precise and reproducible way what it actually measures – completely disregarding whether it measures what it is supposed to measure.

Reliability is a function of the degree to which systematic and chance variations have been controlled in the measurement. These variations, in turn, depend on two factors: the actual measurement (comprising the measuring instrument, [illegible] user, and the circumstances) and the object of the measurement. Sometimes, the term reliability is used in a narrow sense to denote only factors related to the actual measurement, the term constancy covering factors related to the object of measurement. In quality assurance, constancy usually does not present particular problems, the source documents usually being invariable medical records. Constancy may be a problem in connexion with participatory observation or attitude surveys.

There are two basic measures of the reliability (in the narrow sense) of a measuring instrument: the coefficient of equivalence and the coefficient of stability. These are measures of correlation between the results of two or more interdependent measurements. To obtain the value of the coefficient of equivalence, several persons may simultaneously use the same instrument or one or more persons may simultaneously use two or more equivalent instruments. To obtain the value of the coefficient of stability, the original measurement is repeated after a certain lapse of time.

Sensitivity

Sensitivity refers to the ability of a measuring instrument to detect differences in the variable to be examined. Both good validity and reliability increase the sensitivity of the instrument. If the instrument measures something else than what is assumed (i.e. its validity is low) it is very unlikely that differences will be detected, however high the reliability may be. Correspondingly, a great amount of chance variation (i.e. poor reliability) may effectively conceal true differences even when the instrument is valid.

Sensitivity may be increased by means of a battery of more-or-less closely related measuring instruments instead of just one. In quality assurance, this means increasing the number of criteria used. The result of this approach, however, may be that the measurement becomes too time-consuming and expensive. To avoid this, the correlation of each criterion in the measurement battery with the score yielded by the entire battery can be computed, and those with the highest correlation selected for routine use. This approach is particularly applicable in the case of process analysis. Factor analysis has also been used to maximize the information value of the final set of criteria. A comprehensive set of criteria can be subjected to factor analysis. Within each resulting factor, discrimination analysis can be performed to determine those criteria that best measure this factor.

EDUCATION FOR QUALITY ASSURANCE[a]

Medical education

The inclusion of quality assurance in medical education has three main objectives: to create an attitudinal atmosphere favourable for the adoption of quality assurance, to teach the professionals to use the results of quality assurance, and to teach at least some of them to implement it.

According to educational psychology, the permanence of learned behaviour depends on the conditions under which the learning has taken place. In this respect, three modes of learning can be distinguished: compliance, identification and internalization (*7,167*).

Compliance can be said to occur when an individual accepts influence because he hopes to achieve a favourable reaction from another person or group. This may be the case with quality assurance techniques relying on peer acceptance and comparison with peer results. The individual tends to exhibit such behaviour only under conditions of surveillance by the influencing agent. This may explain the lukewarm and half-hearted acceptance of peer methods and the relatively poor results.

In *identification*, an individual accepts influence because he wants to establish or maintain a satisfying relationship with another person or group. This mechanism can be used by providing the students with role models during education. If an esteemed teacher accepts and uses quality assurance methods, the students may adopt corresponding behaviour. Behaviour adopted through identification may, however, lose its significance as soon as the original relationship ceases, such as when the student leaves the medical school.

Internalization means that the student accepts influence because the content of induced behaviour is intrinsically rewarding for him, and it is congruent with his value system. When an individual adopts behaviour through internalization, he tends to perform it under conditions of relevance of the issue, regardless of surveillance or the salience of the issue for some relationship. Internalization may be the only means to achieve permanent results in teaching quality assurance. Perhaps the most important content of such education is not the various techniques of quality assurance but a self-critical attitude. To achieve this, students should be exposed to a wide variety of critical literature from, say, Illich (*168*) and Fuchs (*169*) to McKeown (*170,171*) and Cochrane (*1*) and forced to defend themselves with regard to the issues raised by the critics of medicine.

Some experimental quality assurance teaching programmes (*172,173*) have provided important lessons concerning the best way to arrange training. Perhaps the most important problem is proper timing. An obvious corollary of the emphasis on internalization is that quality-related education should take place relatively early in the curriculum. One has, however, to balance two considerations. On the one hand, as Cooper (*174*) has noted, the earlier a physician is introduced to quality assurance, the more likely he will accept it as a normal pattern and the less threatening it will become in practice. On the other hand, the issue has to be relevant for the students. In the early stages of their career, students do not see the relevance of quality assurance for their future professional role. A major requirement for successful quality assurance-related education seems to be that the students already have clinical experience and clinical responsibility. If they are to develop criteria of good care, they should have at least a modicum of input into policy-making and implementation in quality assurance. The introduction of quality assurance should be staged, taking into account the aptitude of the medical students and progressing from imparting self-critical attitudes to the development of process-related criteria. The outcome-related quality assurance methods should be left to the last stage, perhaps to postgraduate training. The successful use of medical records in auditing the quality of care presumes that the importance of complete and reliable records is emphasized as a part of the training.

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[a] **This section draws heavily on material by the author previously published elsewhere (*29*).**

A major difficulty in quality assurance-related training is the atmosphere in medical schools. A defensive attitude towards criticism, including self-criticism, often prevails. Relatively few teachers are genuinely interested in and capable of implementing quality assurance; as a consequence, students lack appropriate role models. As an editorial in the *Lancet* (*175*) put it, "the enemies of audit are those who teach didactically and, by a kind of public bullying or mockery on a ward round, deter students from the habit of continual questioning . . . In the end, the responsibility for effective internal audit rests squarely on the shoulders of the universities, the medical schools, and perhaps above all on those responsible for postgraduate training in general practice. Without a willing spirit of inquiry, audit is worthless". Only when self- and peer-evaluation becomes an explicit role task for future physicians, will the learners be likely to apply to their own clinical performance the attitudes, knowledge and skills they have learned in quality-related training. As in so many other areas of education, teaching the teachers first might be the most effective strategy.

The consensus of those educators who have experimented with quality assurance programmes as a part of medical education seems to be that the problems are considerable but not insurmountable and that, once they have been overcome, quality assurance can constitute a most effective way to integrate medical practice and medical education.

Education of the public

The education of the public in quality-related questions can aim at increasing self-care, promoting proper utilization of available services, creating quality-consciousness, and advancing the acceptance of quality assurance. Some of these goals, such as the promotion of proper utilization, are primarily economic but have quality connotations as well. In discussing the role of the consumer there is a curious paradox. On the one hand, it has been emphasized that the public has an obligation to maintain its health and to discern low quality services from high quality services (*168,169*); on the other hand, it has been claimed that one of the characteristics of health care is the consumer's ignorance of the true value and quality of the services he uses (*151*). This ignorance has been used as a justification for refusing consumers the right to participate in setting qualitative standards.

The ignorance claim in itself reveals a clear need to promote both self-care and quality consciousness. Self-care has been defined as a process whereby lay persons can actively function for themselves or others to prevent, detect or treat disease, and promote health so as to supplement or substitute for other resources (*177*). Procedures that have been taught to the public include, for instance, diagnosis of common conditions, giving injections, urine testing, first-aid tasks, taking of blood pressure, obtaining throat cultures, and kidney dialysis. The performance of such tasks by lay people may have the following qualitative benefits: reduction in broken appointments and in malpractice suits; more appropriate utilization of health services, including more appropriate patient-initiated contacts; increased compliance with recommended treatment; and greater community support for health care programmes.

The quality consciousness of consumers is clearly increasing. One obvious reason is the rising educational level of the public. The healthy public is also increasingly interested in the provision of health services, i.e. people are no longer acting only as patients but as consumers.

Earlier in this report, I tried to reserve a place for consumers in the various standard-setting bodies, such as audit committees or licensing bodies. Consumer representatives participating in such activities need special training to be able to assess critically the value and quality of health services, to identify consumer standards of high quality, and to translate them into objectives of care.

The incongruence between the expectations of consumers and professionals is an important facet of the possible qualitative inadequacy of health services. It seems to me that the problem has often been turned upside down. Consumers are held responsible for unsatisfactory results because they are ignorant, they do not comply or they malinger. The task of education is considered to be to teach ignorant consumers to accept and assimilate the values and qualitative standards of the professionals, and to demand care that adheres to these standards. The more burning problem, however, may well be that professionals are ignorant of, and insensitive to, the needs and wishes of the consumers and should be educated to recognize and respect them.

The dominance of professional values and standards is especially prominent in the area of compliance with a prescribed regimen. Literature on compliance is replete with explicit or implicit references to the Parsonian definition of the role of the patient, according to which the patient is expected to seek competent help, to accept the authority of the professionals, and to comply with the physician's instructions (*178*); for example ". . . in return for physician's services the patient is expected to cooperate in these endeavors, pay a fee for services rendered, and comply with the doctor's medical directives" (*179*). There is no doubt that the patient's compliance with the prescribed regimen may determine the outcome of the care, but a sober second look should be taken at the remedies suggested for curing non-compliance. Sometimes patient education may well be the most appropriate remedy, but there certainly are cases when the providers are those who need education on the elements of a successful doctor–patient relationship. Davis (*179*) found that younger physicians are more ready than their older colleagues to accept the idea that non-compliance is not always a patient's fault but may result from their own shortcomings.

5

Conclusions

The following conclusions concerning the "state of the art" of quality assurance in Europe, based on site visits and supporting material, should be viewed in the light of the limitations of the study. In addition, they describe an artificial "average" situation, which means that there may be exceptions.

Interest

There is a clear interest in the quality of health services, as shown by existing routine and pilot programmes as well as by ongoing research and discussion. This interest has, however, not been translated into an explicit policy.

Policy

The main reasons for the discrepancy between interest and policy appear to be:

(*a*) too broadly defined or non-existent qualitative objectives;

(*b*) lack of knowledge of the existence of available quality assurance methods;

(*c*) limited confidence in the capability of such methods to accomplish anything worthwhile;

(*d*) belief in the qualitative adequacy of the current system and a concomitant belief in negligible variation in the quality of health services; and

(*e*) indifferent or hostile attitudes, especially on the part of the medical profession.

Assumed qualitative adequacy

There are several good reasons why health authorities and health professionals can sincerely believe that the quality of health services does not present any particular problems:

(*a*) the relatively small size of many European countries, making it easy to identify institutions and personnel providing poor quality services;

(*b*) the relatively uniform educational system;

(*c*) the existence of several built-in (primarily structural) checks such as

- strict selection in many educational institutions (especially medical schools)
- national examination before graduation
- mandatory licensing of personnel and institutions
- mandatory continuing education
- mandatory specialization (especially in the socialist countries)
- professional promotion based on merit and peer review

(*d*) centralized health planning in many countries, permitting the application and enforcement of uniform (primarily structural) standards; and

(*e*) a completely or partly state-subsidized system in many countries, providing the health authorities with the means to exert control over the system and to enforce regulations.

Growing concern

In spite of the above factors, there is a growing awareness among health authorities and health professionals that the quality of health services is not quite as problem-free as is often assumed. The following factors have been the main contributors to this development:

(*a*) broader definition of the quality of health services – equity and efficiency have become new and important foci of interest;

(*b*) unexpectedly large variations in many quality-related variables, as revealed by *ad hoc* studies;

(*c*) increasing consumer interest and participation in the production of health services;

(*d*) increasing costs of health care, resulting primarily in a new emphasis on the efficiency of the system but also in attempts to guarantee that what is produced is qualitatively adequate; and

(*e*) economic cooperation among European countries, especially common labour markets.

The concept of quality

This varies greatly among the countries of Europe. The poorer countries give the highest priority to equity, regardless of their political system, and may even consider a high level of scientific-technical quality a luxury that they cannot afford; the richer countries emphasize medical excellence, which manifests itself in the form of reliance on high technology and specialization, although many of them are beginning to question the wisdom of providing "the best for everyone". Increasing attention is being paid to the concepts of optimal and logical quality. It has even been officially suggested that the scientific-technical quality of care could be lowered in many instances without any adverse effects on the recipients of care.

The motivation for quality assurance

The prime motivation of quality-related activities, especially of new or contemplated activities, is either improved scientific-technical quality of care or increased efficiency, i.e. an economic motivation. In many cases, these two juxtaposed trends can be discerned within a country: the medical profession (sometimes also the consumers) pushes for maximum quality, the health authorities for optimal quality or a minimum acceptable and effective level of care. This discrepancy in motivation and objectives is a source of potential conflict.

Strategies to influence care

Most of the strategies are at the level that guarantees minimum standards. Trust in education as a means to improve the quality of care is unshaken, although the content of education – and especially that of continuing education – is seldom geared to the real educational needs of health professionals. Specific quality assurance programmes are sporadic and non-systematic, based on individual initiative. However, the number of such programmes is increasing and national health authorities are becoming interested in them.

Sponsorship of quality assurance programmes

The bulk of quality assurance programmes in Europe are sponsored by the national health authorities. An inevitable corollary is that they are often concerned only with minimum standards. The professional associations are relatively inactive, sometimes even hostile, but individual professionals have pioneered in introducing some specific quality assurance programmes. So far, the consumers have been interested primarily in the equity and accessibility of health services, but there are signs that they are becoming more sophisticated and quality conscious.

Locus of quality assurance programmes

Macro-level programmes, such as licensing, usually concern all institutions and the entire personnel. Micro-level programmes, when they exist, tend to be limited to hospitals, leaving private practice and public primary care outside their scope. It may well be, however, that there is a much greater need for quality assurance in private practice, primary care and peripheral health care institutions, since there is probably more variation in the quality of care than in large hospitals.

Causes of problems and types of available remedial action

There appears to be a great tendency to see only one reason for poor performance: lack of knowledge. This is a natural result of the fact that the methods used are primarily geared to revealing cognitive deficiencies. The obvious consequence of this narrow approach is that education is considered almost the only possible remedial action. Unfortunately, the exact composition and dose of this remedy is seldom directly linked to correction of the specific weaknesses revealed by assessing the quality of the actual performance.

Training in quality assurance

No European country has instituted systematic training in quality assurance. This may be one of the most important reasons for the lack of interest in quality assurance characteristic of the majority of health professionals.

Statistical methods v. case reviews

In many European countries, the health authorities are relatively satisfied with the type and amount of statistical quality assessment currently employed, but there is a generally felt need to institute more methods of the case review (i.e. medical audit) type.

"State of the art" – summary

There is a great amount of interest, a considerable number of research activities and some pilot programmes, and a fair amount of quality-related activities, but very few activities that could be called quality *assurance* in the narrow sense of the word. The lack of cross-fertilization among research, policy-making, and practice is conspicuous.

For the development of quality assurance, there must exist a clearly expressed political will, specifying the component of quality that should have the highest priority. The research community has to pick up leads from this political will and from the health care practices to clarify the concept of quality *per se*, to identify factors influencing the quality of health services, and to develop methodologically sound quality assurance methods. The education system has to transmit the knowledge and skills thus gained to the practitioners. It would be advantageous if the practitioners themselves were responsible for implementing the programmes. Finally, the experiences gained in practice have to be fed back to the decision-making process, research and education.

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